

Contributor:

Tom Cantu

U.S. Regulatory Affairs, GlaxoSmithKline

Rationale: I copied and pasted the content of the FDA's Rheutopia CMI prototype into an alternate format of CMI. The layout of this alternate format has been evaluated in a small study (referenced below). This study showed that patients were able to navigate this document and find information reasonably well. Like the FDA prototypes, it utilizes many of the principles for effective communication: a Q&A format, bullet points, and adequate use of white space. We feel this version may be an enhancement of the FDA's Prototype #3 because our version provides a "visual index" of the information in the document by listing each question in the left hand column. Also, by putting the "answers" in boxes in the right hand column, our version may help to guide the reader's eye through each topic. We have not done any study assessing whether one format of CMI is better than another format.

Reference: Papay, Julie I., et al. Assessment of a Simplified Format of Written Patient Prescription Drug Information. *Drug Information Journal*, 2010; 44:375 – 391

Rheutopia [pronounced Roo-TOH-pee-ah] (arixalate)

What does Rheutopia treat?	<p>Rheutopia treats:</p> <p>Rheumatoid arthritis. It reduces pain and swelling in joints, slows joint damage, and may improve your ability to do physical activities.</p> <p>Juvenile rheumatoid arthritis in children at least 4 years old. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.</p> <p>Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility</p> <p>Plaque psoriasis in adults. Rheutopia improves or clears up areas of skin with psoriasis. .</p>
Important Warnings	<ul style="list-style-type: none"> Rheutopia can weaken your immune system, and make you more vulnerable to infections. Do not use Rheutopia if you have an active infection. Some people taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections. Call your doctor right away if you get a fever or feel like you may be getting an infection.
What should I tell my Doctor?	<p>Before taking Rheutopia, tell your doctor if you:</p> <ul style="list-style-type: none"> have an infection, or think you have an infection (such as a cold, flu or skin infection). have TB or have been near someone who has TB. You may need to be tested and treated for TB. lived in or traveled to other countries. There is more risk for getting TB or other infections in certain countries. have any nervous system or heart problems. are taking the medicine Kineret (anakinra). The risk of getting a serious infection is increased if you take Kineret with Rheutopia. are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.
When should I call my Doctor?	<p>Stop taking Rheutopia and tell your doctor right away if you develop:</p> <ul style="list-style-type: none"> Fever, cough, flu-like symptoms, or a skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection. Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse. Chills, swollen lymph nodes, night sweats, fever, or weight loss. You may have a higher chance of getting lymph node cancer. Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding. Shortness of breath, swelling of ankles or feet, or sudden weight gain. These are symptoms of heart failure that may develop or get worse. Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.
What are some common side effects?	<ul style="list-style-type: none"> Redness, rash, swelling, itching or bruising where the shot was given. Headache Runny nose <p>Tell your doctor about any side effect that does not go away in a few days or gets worse.</p>
How do I use Rheutopia?	<ul style="list-style-type: none"> Rheutopia is an injection (shot). Do not use Rheutopia until you have been shown how to give a shot. Store Rheutopia in the refrigerator. Do not shake or freeze. If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time. Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.
Where can I get more information?	<ul style="list-style-type: none"> Visit www.fda.more-information.gov Call 1-800-(manufacturer).

You may report side effects to (manufacturer) at (phone # / web address) or to FDA at 1-800-332-1088.

Contributor:

Kala Paul

The Corvallis Group, LLC

Rationale:

The prototype includes elements of the following: the wording of Prototype I, and my own sense of what was esthetically more attractive and inviting to read within the confines of a printable document. The prototype was built on my experience with patient reading medicine information in various formats for comprehension testing (unpublished proprietary data) and my own sense of what I would be likely to read if presented with a paper or electronic document. Actual content for wording, order, or overall simplification was not a consideration in this possible design.

I was unable to find literature that cited one format of information delivery that was superior to another with the proviso that formats followed some basic tenets of health literacy presentation and appropriate information delivery design, some of which I pointed out below.

In providing information for the patient, it is not only vital to get the words and information correct and cognitively accessible, it is important to make the document inviting to read. The FDA prototypes, while they do follow many principles of plain language communication, are not particularly engaging from the visual standpoint of the reader. Here are what advantages and elements I see in a more compelling format:

1. Keeps information on one page
2. Two-column format with short scan of information in column (30-50 characters and spaces)
3. Uses more of page than FDA prototype, preferable to single column format of "drug facts" box for low literacy reader
4. Clear demarcation of the serious adverse event warning with icon and line thickness, heading and wording caps and centering
5. Clear delineation of the sections with numbering to draw the reader through the document
6. Use of "bubbles" to delineate sections so that maximum use of space is made with preservation of navigation aids (numbers, large headings, larger font), No large areas of "real estate" are left open
7. Enlarged titles for sections to aid navigation
8. Space available for more detail without going over 1 page
9. Information visually balanced so that reader is not distracted by "popping" fonts, bolding, colors, etc
10. Color enhances but does not overwhelm messages
11. Header and footer elements can be combined to add space to page for items such as called out pregnancy information, more detail in "how to use" section

Reference: Elements listed above described in Suitability Assessment of Material from Chapter 4, "Assessing Suitability of Materials" in *Teaching Patients with Low Literacy Skills*, 2nd ed., p41-60. Doak, CC, Doak, LG, Root JH. JB Lippincott Company, Philadelphia, 1996.

PATIENT INFORMATION**Rheutopia™ [Roo-TOH-pee-ah] (arixalate)****IMPORTANT WARNING:
SERIOUS INFECTIONS**

Do not use Rheutopia if you have an active infection.

- Rheutopia affects the immune system. It can make it harder for you to fight infections.
- People taking Rheutopia have gotten serious infections, such as tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

1. What does RHEUTOPIA treat?

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, makes it easier to move around and do physical activities.
- Polyarticular juvenile rheumatoid arthritis (JRA) in people older than 4 years of age who did not have good results from other medicines. Rheutopia reduces pain and the number of painful joints, makes it easier to move around.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and makes it easier to move around.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

2. What should I tell my doctor?

Before using Rheutopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection, such as a cold, flu or skin infection
- have TB or have been near someone who has TB
- lived in or traveled to other countries
- have any problems with your muscles, nerves or heart?
- take the medicine Kineret (anakinra) for arthritis
- are supposed to get a vaccine, such as a flu shot. You should not get *any* vaccines while taking Rheutopia.

3. When should I call my DOCTOR?

Stop using Rheutopia and call your doctor right away for:

- Fever, cough, flu-like symptoms,
- Skin infection (red, warm, painful skin or open sores)
- Chills, swollen lymph nodes, sweating at night, fever, or weight loss
- Numbness, tingling in toes and fingers, or weakness in arms or legs
- Feeling dizzy
- Problems with vision
- Bruising, bleeding, or your skin or gums look pale
- Shortness of breath, swelling of ankles or feet, or sudden weight gain
- Chest discomfort or pain
- Joint pain
- Rash on your cheeks or arms

4. What are some common side effects?

- Redness, rash, swelling, itching or bruising where the shot was given
- Headache
- Runny nose

Tell your doctor about any side effect that does not go away in a few days or gets worse.

5. How do I use RHEUTOPIA?

- You get Rheutopia is a shot. Do not use Rheutopia until your doctor or nurse shows you how to give the shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

6. Where can I get more information?

- Visit www.fda.more-information.gov
- Call 1-800-(manufacturer).

Contributor:

Theo Raynor

University of LEADs, Luto Research, Ltd.

Rationale:

I have not meddled too much with the content – I would like to do more work on the wording, but wanted to concentrate on making points about layout.

- If you put the original and my version side-by-side you will see the impact of the white on black headings – they stand out so much better and the different sections are easy to identify.
- Slightly increasing the space between the lines has an impact on how easy the document looks to read – if it looks hard, some people won't even try.
- I have taken the liberty of moving the 'Black box' to second place – it is still prominent, but the patient first sees the benefits of the medicine

Information for the Patient: Rheutopia

[Roo-toh-pee-ah] (also known as arixalate)

What does Rheutopia treat?

- **Rheumatoid arthritis in adults.** It reduces painful & swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- **Polyarticular juvenile rheumatoid arthritis (JRA)** in people older than 4 years of age who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- **Ankylosing spondylitis.** Rheutopia reduces back pain, swelling, and improves mobility.
- **Plaque psoriasis in adults** who may benefit from medicines or having photo-therapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious infections

Rheutopia affects the immune system. It can lower your ability to fight infections. **Do not use Rheutopia if you have an infection at the moment.** People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

What should I tell my doctor?

Check with your doctor before using Rheutopia if:

- You have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- You have TB or have been near someone with TB. You may be tested and treated for TB. Also tell your doctor if you have lived in or travelled to other countries. You are more likely to get TB or other infections in certain countries.
- You have any nervous system or heart problems.
- You are taking the medicine Kineret (anakinra). The risk of serious infections increased when used with Rheutopia.
- You are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.

When should I call my doctor?

Stop using Rheutopia and tell your doctor right away if you get:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be signs of a serious infection.
- Feeling numbness, weak, dizzy, tingling or vision problems. Signs of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss. You may have a higher chance of getting lymph node cancer.
- Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain. These are signs of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be signs of a serious immune reaction.

What are some common side effects?

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache or runny nose

Tell your doctor about any side effect that does not go away in a few days or gets worse.

How do I use Rheutopia?

Rheutopia is an injection (shot). Do not use until you have been shown how to give a shot. Your doctor will tell you how often to have it.

- Store in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Do not use Rheutopia more often than prescribed.

Where can I get more information?

Visit www.fda.more-information.gov or call 1-800-(manufacturer). You may report side effects to (manufacturer) or FDA at 1-800-332-1088.

Contributor:

Theo Raynor

University of Leeds, Luto Research, Ltd

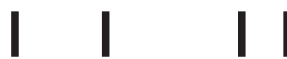
Rationale:

I would strongly recommend that you consider using a two-sided leaflet – assuming you are constrained to just one sheet of paper.

- This leaflet is what we call the “Birthday Card” format – the paper is in landscape format and is folded in half – with a front page, two middle pages and a back page. In testing people say they like this format – “its like reading a book”.

Accolate™ 20mg Film-coated Tablets

zafirlukast



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Accolate is and what it is used for
2. Before you take Accolate
3. How to take Accolate
4. Possible side effects
5. How to store Accolate
6. Further information

1. What Accolate is and what it is used for

Accolate contains a medicine called zafirlukast. This belongs to a group of medicines called 'leukotriene antagonists'. This means that it reduces the effects of 'leukotrienes'. These are natural substances in the lung that cause asthma.

- Accolate is used to control the symptoms of your asthma.
- It is also used to prevent your asthma from getting worse.

Do not take Accolate to treat sudden (acute) asthma attacks. Your doctor will provide you with other medicines to treat sudden attacks.

2. Before you take Accolate

Do not take Accolate if:

- You are allergic (hypersensitive) to zafirlukast or any of the other ingredients of Accolate (listed in Section 6: Further information).
- You have ever had problems with your liver.
- You have had problems with your liver that were caused by taking Accolate.

Do not take Accolate if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Accolate.

Take special care with Accolate

Check with your doctor or pharmacist before taking Accolate if:

- You are a smoker. This could affect the amount of Accolate that you need to take.
- You have kidney problems.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Accolate.

If you go into hospital let the medical staff know that you are taking Accolate.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Accolate can affect the way some medicines work and some medicines can have an effect on Accolate.

- In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Theophylline (used to treat asthma).
 - Erythromycin (an antibiotic).
 - Terfenadine (used to treat hayfever).
 - Warfarin (used to thin the blood).
 - Aspirin (if you are taking it frequently as a painkiller).

Pregnancy and breast-feeding

- Talk to your doctor before taking Accolate if you are pregnant or may become pregnant. Your doctor will decide whether you can take Accolate during this time.
- Do not take Accolate if you are breast-feeding.

Driving and using tools and machines

Accolate is not likely to affect you being able to drive or use any tools or machines.

3. How to take Accolate

Always take Accolate exactly as your doctor has told you. Read the label on the container to remind you what the doctor said. You should check with your doctor or pharmacist if you are not sure.

Accolate should not be given to children under the age of 12 years.

If you have been taking other medicines for asthma, do not stop taking them unless your doctor tells you that you can.

Taking this medicine

- Take Accolate every day as prescribed by your doctor.
- The usual dose is one 20mg tablet taken twice a day. This is usually one tablet at the start of the morning and one tablet last thing at night.
- Try to take your medicine at the same times each day.
- Swallow each tablet whole with a drink of water.
- Do not take your tablets with a meal.

If your asthma gets worse while you are taking Accolate, follow the advice that your doctor has given you for treating sudden (acute) asthma attacks and see your doctor as soon as possible.

If you take more Accolate than you should

If you take more Accolate than prescribed by your doctor, ask your doctor or pharmacist for advice.

If you forget to take Accolate

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

Stopping Accolate

- Continue to take Accolate even when your asthma is not causing you any problems.
- Do not stop taking your tablets when you are feeling well, unless your doctor tells you to.

4. Possible side effects

Like all medicines, Accolate can cause side effects, although not everybody gets them. The following side effects can happen with this medicine.

Allergic reactions (uncommon, affecting less than 1 in 100 people)

The signs include:

- Skin rash and itching.
- Swelling caused by a build up of fluid. This is also known as ‘oedema’.

If any of these happen, **stop taking Accolate and tell your doctor straight away.**

Blood problems (rare, affecting less than 1 in 1,000 people)

The signs include:

- Bruising more easily.
- Bleeding disorders, including heavy menstrual periods.
- A high temperature (fever) that does not go away.
- Sore throats which happen often.

If any of these happen, **tell your doctor straight away.**

Liver problems (rare, affecting less than 1 in 1,000 people)

Rarely, people taking Accolate get liver problems. These problems range from non-serious changes to your liver (shown in blood tests) to serious conditions such as liver failure. A very small number of people have died from liver failure.

Your doctor may ask you to have blood tests before and during treatment with Accolate to check whether there are any problems with your liver.

The signs of liver problems include:

- Yellowing of your skin or the whites of your eyes (jaundice).
- Pain on the right side of your stomach and just below your ribs.

If any of these happen, **tell your doctor straight away.**

If you notice any of the following, and they do not go away, this might also mean that you have liver problems:

- Loss of appetite.
- Feeling itchy.
- Feeling tired, having no energy or feeling like you have flu.
- Feeling as though you are going to be sick or actually being sick.

If any of these happen, and they do not go away, **talk to your doctor or pharmacist.**

Unusual conditions

Unusual conditions called ‘Churg-Strauss syndrome’ and ‘eosinophilic pneumonia’ have been seen in a very small number of people taking Accolate for asthma. The signs include a combination of the following:

- Sinusitis. This can cause a feeling of fullness in the nose, cheeks and behind your eyes.
- Feeling like you have flu.
- Feeling more and more breathless.
- Pain in the area of your stomach or gut.
- Skin rash.
- A feeling of ‘pins and needles’ or numbness of your arms or legs.

If you notice more than one of these signs, **tell your doctor straight away.**

Other possible side effects:

Common (affects less than 1 in 10 people)

- Feeling of discomfort or generally feeling unwell.
- Stomach and gut problems, such as feeling or being sick, diarrhoea or stomach pain. These effects are usually mild.
- Headache. This is usually mild.
- Chest infections.
- Difficulty sleeping.

Rare (affects less than 1 in 1,000 people)

- Bruising.
- Pain in the joints or muscles.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Accolate

- Keep your tablets in a safe place where children cannot see or reach them.
- Do not store above 30°C.
- Keep your tablets in the container they came in.
- Do not use Accolate after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

6. Further information

What Accolate contains

The active substance is zafirlukast. Each tablet contains 20mg of zafirlukast.

The other ingredients are croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, povidone, titanium dioxide.

What Accolate looks like and contents of the pack

Accolate tablets are white, round and film-coated.

Accolate comes in containers of 56 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Accolate is held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

Accolate is manufactured by AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Accolate 20mg Film-coated Tablets**

Reference number 17901/0001

This is a service provided by the Royal National Institute for Blind People.

Leaflet prepared: September 2009

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Accolate is a trade mark of the AstraZeneca group of companies.

RSP 09 0060

AstraZeneca 

Contributor:

Theo Raynor

University of Leeds, Luto Research, Ltd

Rationale:

- This has a "Headline Section" titled "**Important things you should know about Creon 10000**". This highlights the most important points about the medicine – so it is not totally negative. Although safety information is important and deserves prominence, having an entirely negative introductory section is not the way forward I feel
- White on black headings very effectively demarcates the different sections i.e. there are clearly visible between the black bars. Our testing experience shows that people find this very helpful. Also the clear bold sub-headings prove effective in testing.
- There is a contents section: "**How to find the information you need**". In testing, people say they find this very helpful.
- Judicious use of bullets - overuse of bullets renders them less effective
- Multiple column landscape format - we find using multiple columns in landscape (4 or 5) maximizes the amount of information that can be contained, while maintaining readability.

PB Creon 10000 Kps GB 02
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P-036-5
supersedes: 1038336

Patient Information Leaflet

creon[®] 10000
capsules
Pancreatin

Important things you SHOULD know about Creon 10000

- Creon 10000 is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- **Take** the amount of capsules as prescribed by your doctor or dietician.
- **Take** Creon 10000 with a meal or a snack and drink plenty of water.
- **Do not take** Creon 10000 if you are allergic to pork or any pig product.
- If you experience **severe abdominal pain** while taking Creon 10000, contact your doctor immediately.
- Most people do not have problems taking Creon 10000 but side effects can occur. (see section 4)

Please read the rest of this leaflet carefully before you start taking these tablets. It includes other important information on the safe and effective use of this medicine that might be especially important for you.
This leaflet was last approved in ????

Format 300 x 141 mm
plano
Papiergewicht 50 g/m²
Black, **Pantone 347 CV**

How to find the information you need

- 1. About Creon 10000**
What Creon 10000 is and how it works.
- 2. Before you take Creon 10000**
Who can take Creon 10000?
Can you take Creon 10000 if you are pregnant or breast feeding?
Driving or operating machinery.
- 3. How to take Creon 10000**
How much Creon 10000 you should take.
When you should take Creon 10000.
How you should take Creon 10000.
What to do if you take too much Creon 10000.
What to do if you forget a dose.
- 4. Possible side effects**
Abdominal symptoms (such as abdominal pain).
Side effects and what to do if you get them.
- 5. How to store Creon 10000**
How and where to keep your capsules.
- 6. Further Information**
The ingredients in Creon 10000.
More information about cystic fibrosis and pancreatitis.

This medicine has been prescribed for you personally. Don't offer it to other people, even if their symptoms seem to be the same as yours.

1. About Creon 10000

- What is Creon 10000**
- Creon 10000 is a high strength pancreatic enzyme supplement.
 - Pancreatic enzyme supplements are used by people whose bodies do not make enough of their own enzymes to digest their food.
 - Creon 10000 granules contain a mixture of the natural enzymes which are used to digest food.
 - The enzymes are taken from pig pancreas glands.

How does Creon 10000 work?

The enzymes in Creon 10000 work by digesting food as it passes through the gut. So, you must take Creon 10000 at the same time as eating a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. Before you take Creon 10000

- Do not take Creon 10000 if:**
- Your doctor has told you that you are in the early stages of inflammation of the pancreas (acute pancreatitis)

- You are allergic to pork or any pig product
- If any of the above applies to you do not take Creon 10000. Talk to your doctor or dietician again.

Talk to your doctor if:

- you are pregnant or trying to get pregnant
- you are breast feeding

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Please tell your doctor, dietician or pharmacist if you think that you should not take Creon 10000 for any other reason.

If you drive or use machines

It is unlikely that Creon 10000 will affect your ability to drive or operate tools or machines.

3. How to take Creon 10000

How much Creon 10000 to take

- **Always follow your doctor or dietician's advice on how many capsules to take.**
- If your doctor advises you to increase the number of capsules you take, you should do so slowly. If you still have fatty stools or abdominal pain, talk to your doctor or dietician.

When to take Creon 10000

- Always take Creon 10000 at the same time as eating a meal or a snack and drink plenty of water (see section 1).

How to take Creon 10000

- Swallow the capsules whole or
- Open the capsules and mix the granules with soft food. Swallow the mixture straight away, without chewing.
- Drink plenty of liquid every day.

How long to take Creon 10000 for

You should take your medicine until your doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

Please
turn over

PB Creon 10000 Kps GB 02
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P-036-5
supersedes: 1038336

Format 300 x 141 mm
plano
Papiergewicht 50 g/m²
Black, Pantone 347 CV

If you take too much Creon 10000

If you take too much Creon 10000 you should drink plenty of water and see your doctor immediately.

If you forget a dose

If you forget to take your medicine, wait until your next meal and take your usual number of capsules. Do not try to make up for the number of capsules that you have missed. **Just take your next dose at the usual time.**

4. Possible side effects

Like all medicines, Creon 10000 can cause side effects (unwanted effects or reactions), but not everyone gets them.

If you have severe or long-lasting abdominal pain, contact your doctor immediately.

Fibrosing colonopathy

A rare bowel disorder called fibrosing colonopathy was reported in a small number of children, with cystic fibrosis, who took large doses of both high and low-strength enzymes. However, this is **not** known to happen to children taking Creon 10000.

If you notice any **unusual abdominal symptoms** while taking Creon 10000 – contact your doctor.

Inform your doctor if you have:

- diarrhoea
- constipation
- stomach pains

- feeling sick

- skin reactions, such as a rash or itching

Rare side effects (less than 1 in 1000 patients):

- developing high levels of uric acid in your blood and urine

If you notice any unwanted effect (even one not mentioned in this leaflet), or if you feel unwell while taking Creon 10000: **Tell your doctor.**

5. How to store Creon 10000

How and where to keep your capsules
Keep all medicines out of the reach and sight of children – preferably locked in a cupboard or medicine cabinet.

Do not store above 30°C and keep in the original container. The enzymes in Creon 10000 are natural products and their ability to digest food decreases over time. If the container is left in warm conditions (e.g. the glove compartment of a car), the digestive activity decreases faster.

Do not take Creon 10000 capsules after the expiry date on the bottle.

Return all unused medicine to your pharmacist.

6. Further information

The ingredients in Creon 10000

The active ingredient in Creon 10000 is pancreatin. Each capsule contains enteric coated brownish-coloured granules (minimicrospheres) containing pancreatin 150 mg, equivalent to:

List of Enzymes: (PhEur units per capsule)

Lipase 10,000

Amylase 8,000

Protease 600

The granules are coated with a mixture of the following ingredients: macrogol 4000, light liquid paraffin, hypromellose phthalate, dibutyl phthalate and dimeticone.

The capsules contain: gelatin, iron oxides (E172), titanium dioxide (E171) and sodium laurylsulphate. Creon 10000 is available in a 100, 250 or 300 capsules packs. Not all pack sizes may be marketed.

The Marketing Authorisation Holder is:

Solvay Healthcare Ltd,
Southampton, SO18 3JD, UK.

The Manufacturer is:

Solvay Pharmaceuticals GmbH,
31535 Neustadt a. Rbge, Germany.

More information about cystic fibrosis and pancreatitis

You can find out more about Cystic Fibrosis from the following organisation:

The CF Trust

11 London Road, Bromley BR1 1BY.

You can find out more about Pancreatitis from the following organisation:

Pancreatitis Supporters Network
PO Box 8938, Birmingham B13 9FW.

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Rationale:

As you seem to be focusing on a one page one side format, I thought this one showed up some interesting points.

- It is landscape, and here there are 6 columns. This allows the inclusion of a large amount of information on just one page.
- The white on black headings and bold sub-headings make navigating round the leaflet very easy.

LIPITOR®

Atorvastatin calcium

This leaflet has been prepared by researchers as part of the Investigating Consumer Medicine Information project. This leaflet does not replace the current Consumer Medicine Information (CMI) leaflet for Lipitor (or Mersyndol). The CMI for Lipitor (or Mersyndol) can be obtained from your pharmacist, doctor or from www.medicine.org.au



Patient Medicine Information

This leaflet answers some common questions about Lipitor. It does not contain all the information about Lipitor.

- It does not take the place of talking to your doctor or pharmacist.
- **If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

1 What Lipitor is used for

Lipitor contains a medicine called atorvastatin. This belongs to a group of medicines called 'statins'.

Lipitor is used to lower the amount of fats in your blood. These fats include cholesterol and triglycerides.

How Lipitor works

Lipitor works by reducing the amount of cholesterol made by the liver. It lowers the 'bad' cholesterol and raises the 'good' cholesterol.

Your doctor may have prescribed Lipitor for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

2 Before you take Lipitor

Do not take Lipitor if:

- you have an allergy to atorvastatin or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include skin rash, itching, difficulty breathing, or swelling of the face
 - you have liver disease
 - you are pregnant, might become pregnant, or are breast feeding
- If you are not sure whether to start taking Lipitor, talk to your doctor.

Tell your doctor if you have any other medical problems including:

- liver problems
- muscle pain, tenderness or weakness from other medicines used to lower cholesterol or triglycerides
- types of stroke called a 'haemorrhagic stroke' or a 'lacunar stroke'

Also tell your doctor if:

- you drink alcohol regularly
- you have allergies to any other medicines or anything else, such as foods, preservatives or dyes.

Taking other medicines

Tell your doctor if you are taking any other medicines or remedies. This includes medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Lipitor. These include:

- antibiotics called erythromycin, clarithromycin and rifampicin
- phenytoin - for epilepsy
- cyclosporin - for suppressing the immune system
- some medicines for fungal infections
- efavirenz and protease inhibitors - for HIV infection
- diltiazem

Your doctor or pharmacist has more information on ALL medicines that affect Lipitor.

Pregnancy and breast feeding

Use a proven method of birth control if you are a woman of child-bearing age. This is because Lipitor may affect your unborn baby if you take it during pregnancy.

If you become pregnant while you are taking Lipitor, stop taking it and talk to your doctor immediately.

Do not take the medicine if you are breast-feeding or intend to breast-feed.

3 How to take Lipitor

Take Lipitor only when prescribed by your doctor.

How much to take

- The usual dose is between 10mg and 80 mg once a day
- Swallow with a glass of water or other liquid.
- You can take Lipitor with or without food.
- Lipitor can be taken at any time of the day
- Lipitor helps lower your cholesterol, but does not cure your illness. This means you must keep taking it, to keep your cholesterol down.

Talk to your doctor or pharmacist if the directions they give you are different from the information in this leaflet.

If you forget to take

- If it is almost time for your next dose, skip the dose you missed. Take your next dose when you are meant to.
- Otherwise, take it as soon as you remember. Then go back to taking your tablets as normal.
- **Do not take a double dose to make up for the dose that you missed.**

If you take too much (overdose)

If you think that you or anyone else may have taken too much Lipitor. You may need urgent medical attention.

Immediately:

- Phone the Australian Poisons Information Centre (telephone 13 11 26)
- Or go to the Accident and Emergency department at your nearest hospital

Do this even if there are no signs of illness or poisoning.

Keep these telephone numbers handy.

4 While you are taking Lipitor

Tell your doctor or pharmacist if you are about to start on a new medicine and you are taking Lipitor.

Food and drink

Alcohol

- Drinking large amounts of alcohol may increase your chance of Lipitor causing liver problems.

Grapefruit juice

- Grapefruit juice makes the body breaks down Lipitor more slowly. Drinking very large amounts (more than 1.2 litres) each day increases your chance of side effects.

Driving or using machines

Lipitor generally does not affect you being able to drive a car or use machines or tools.

However Lipitor may make some people feel dizzy.

Be careful driving or using machines or tools until you know how Lipitor affects you.

5 Side effects

All medicines can have side effects. Ask your doctor or pharmacist to answer any questions you may have about side effects.

Tell your doctor straight away or go to Accident and Emergency at your nearest hospital if you notice any of the following serious side effects:

- swelling of the face, lips, mouth throat or neck which may make breathing or swallowing difficult
- unexpected pain, tenderness or weakness in your muscles not

caused by exercise

- tingling in your hands or feet
- rash or itching.

These serious side effects are rare.

Tell your doctor if you notice any of the following more common side effects and they worry you:

- constipation, diarrhoea
 - feeling unusually tired or weak
 - stomach or belly pain, feeling sick (nausea)
 - headache
 - trouble sleeping
- These are usually mild and do not last long.

Other side effects not listed above may also happen in some patients.

- Tell your doctor if you notice anything else that is making you feel unwell.

6 After using Lipitor

Do not take if the packaging is torn or shows signs of tampering.

Expired medicine

- Do not take if the expiry date (EXP) on the pack has passed.

Storage

- Keep your tablets in the blister pack until it is time to take them.
- **Keep your tablets where young children cannot reach them.**
- Keep Lipitor in a cool dry place where the temperature stays below 25 degrees C.

7 Further information

This is not all the information that is available on Lipitor. If you have any more questions or are not sure about anything ask your doctor or pharmacist. You may also get further information at www.medicines.org.au

What Lipitor tablets contain

The active ingredient of LIPITOR is 'atorvastatin'. The inactive ingredients are calcium carbonate, microcrystalline cellulose, lactose, croscarmellose sodium, polysorbate 80, hydroxypropylcellulose, magnesium stearate, opadry white YS-1-7040, simethicone emulsion, candelilla wax (contained in 10, 20, and 40 mg tablets)

Product description

Lipitor tablets are white oval tablets, marked with:

- 10 mg PD155
- 20 mg PD156
- 40 mg PD157
- 80 mg PD158 (only available in Australia)

Lipitor comes in blister packets of 30 tablets.

Distributor

Lipitor is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free Number: 1800 675 229

® Registered Trademark

Australian Registration Number

10mg AUST R 59603
20mg AUST R 59606
40mg AUST R 59607
80mg AUST R 77326

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