

omeprazol cinfamed 20 mg gastro-resistant hard capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What omeprazol cinfamed is and what it is used for
2. What you need to know before you take omeprazol cinfamed
3. How to take omeprazol cinfamed
4. Possible side effects
5. How to store omeprazol cinfamed
6. Contents of the pack and other information

1. What omeprazol cinfamed is and what it is used for

omeprazol cinfamed contains the active ingredient omeprazole. Which belongs to a group of medicines known as proton pump inhibitors. These medicines act by reducing the amount of acid produced by the stomach.

omeprazol cinfamed is used to treat the following diseases:

In adults:

- “Gastroesophageal reflux disease” (GERD). This condition occurs when stomach acid passes into the oesophagus (the tube that joins the throat to the stomach), causing pain, inflammation and a burning sensation.
- Ulcers in the upper part of the intestine (duodenal ulcer) or in the stomach (gastric ulcer).
- Ulcers infected by a bacterium called “*Helicobacter pylori*”. If you have this disease, it is likely that your doctor will prescribe antibiotics to treat the infection, thus allowing the ulcer to heal.
- Ulcers caused by certain drugs called NSAIDs (non-steroidal anti-inflammatory drugs). Omeprazol can also be used to prevent ulcers from forming if you are taking NSAIDs.
- Excessive stomach acid produced by a tumour in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- “Gastroesophageal reflux disease” (GERD). This condition occurs when stomach acid passes into the oesophagus (the tube that joins the throat to the stomach), causing pain, inflammation and a burning sensation.

In children, the symptoms of the disease may include the return of the contents of the stomach to the mouth (regurgitation), vomiting and insufficient weight gain.

Children over 4 years of age and adolescents

Ulcers infected by a bacterium called “*Helicobacter pylori*”. If your child suffers from this disease, your doctor may prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take omeprazol cinfamed

Do not take omeprazol cinfamed

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in Section 6).
- If you are allergic to medicines that contain proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or esomeprazole).
- If you are taking a medicine that contains nelfinavir (used to treat HIV infection).

Do not take omeprazol if you belong to any of the previous cases. If you are unsure, talk to your doctor or pharmacist before taking omeprazol.

Warnings and precautions

Talk to your doctor or pharmacist before taking omeprazol cinfamed.

Serious skin adverse reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in relation to treatment with omeprazol. Stop taking omeprazol and consult a doctor immediately if you experience any of the symptoms related to the severe skin reactions described in section 4.

Omeprazol can mask the symptoms of other diseases. Therefore, if you experience any of the following complaints before you start taking omeprazol or during treatment, talk to your doctor immediately if:

- You lose weight for no apparent reason and have difficulty swallowing.
- You have stomach pain or indigestion.
- You start to vomit food or blood.
- Your stools are black (faeces stained with blood).
- If you have severe or persistent diarrhoea, as a slight increase in infectious diarrhoeas has been associated with omeprazol.
- You have severe liver problems.
- If you have ever had a skin reaction after treatment with a medicine similar to omeprazol to reduce stomach acid.
- You are due to have a specific blood test (Chromogranin A).

If you take omeprazol for a long period of time (more than 1 year) your doctor will probably carry out regular checks. You should report any new or unusual symptom or circumstances whenever you visit your doctor.

The risk of hip, wrist or spinal column fractures may increase slightly if you are taking proton-pump inhibitors such as omeprazol, especially if you take them for more than one year. Inform your doctor if you have osteoporosis or are taking corticosteroids (which can increase the risk of osteoporosis).

If you develop a rash, especially on areas of the skin that are exposed to the sun, talk to your doctor as soon as possible, as it may be necessary to stop treatment with omeprazol. Remember to mention any other symptom that you may notice, such as joint pain.

When taking omeprazol, inflammation may occur in the kidney. Signs and symptoms may include decreased urine volume or blood in the urine and/or hypersensitivity reactions such as fever, rash and joint stiffness. You should report these signs to the doctor treating you.

Children

Some children with chronic diseases may require long-term treatment, although this is not recommended. Do not administer this medicine to children under 1 year of age or who weigh <10 kg.

Other medicines and omeprazol cinfamed

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes non-prescription drugs. This is because omeprazole can affect the mechanism of action of some medicines and some medicines can affect omeprazole.

Do not take omeprazol if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Inform your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungal infections).
- Digoxin (used to treat heart problems).
- Diazepam (used to treat anxiety, as a muscle relaxant or for epilepsy).
- Phenytoin (used for epilepsy). If you are taking phenytoin, your doctor will have to monitor you when you start or finish your treatment with omeprazol.
- Medicines used to prevent blood clots, such as warfarin or other vitamin K antagonists. Your doctor will need to monitor you when you start or finish treatment with omeprazol.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infection).
- Tacrolimus (in cases of organ transplant).
- Saint John's wort (*Hypericum perforatum*) (used to treat mild depression).
- Cimetazone (used to treat intermittent claudication).
- Saquinavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots (thrombosis)).
- Erlotinib (used to treat cancer).
- Methotrexate (chemotherapy drug used in high doses to treat cancer) - if you are taking a high dose of methotrexate, your doctor will have to temporarily stop treatment with omeprazol.

If, in addition to omeprazol, your doctor has prescribed the antibiotics amoxicillin and clarithromycin to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you inform him/her of the other medicines you are taking.

omeprazol cinfamed with food and drink

You can take your capsules with food or on an empty stomach (see section 3).

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, suspect that you might be pregnant or intend to become pregnant, consult your doctor or pharmacist before taking this medicine.

omeprazol passes into breast milk, but it is unlikely to affect the child when used in therapeutic doses.

Your doctor will decide whether you can take omeprazol if you are breast-feeding.

Driving and using machines

Omeprazol is unlikely to affect your ability to drive or use tools or machines. Side effects such as dizziness and visual disturbances may appear (see section 4). If this occurs, you should not drive or use machinery.

omeprazol cinfamed contains sucrose

This medication contains sucrose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

omeprazol cinfamed contains sodium

This medicinal product contains less than 1 mmol (23 mg) of sodium per capsule; it is essentially “sodium-free”.

3. How to take omeprazol cinfamed

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will indicate how many capsules you should take and for how long. This will depend on your condition and age.

The recommended dose is:

Use in adults

Treatment of the symptoms of GERD, such as **heartburn and acid regurgitation**:

- If your doctor finds that you have slight damage to your oesophagus, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may prescribe a dose of 40 mg for another 8 weeks if your oesophagus has not yet healed.
- Recommended dose once the oesophagus has healed is 10 mg once a day.
- If your oesophagus is not damaged, the recommended dose is 10 mg once a day.

Treatment of **ulcers of the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may prescribe the same dose for another 2 weeks if the ulcer has not yet healed.
- If the ulcer does not fully heal, the dose may be increased to 40 mg once a day for 4 weeks.

Treatment of **stomach ulcers** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may prescribe the same dose for another 4 weeks if the ulcer has not yet healed.
- If the ulcer does not fully heal, the dose may be increased to 40 mg once a day for 8 weeks.

Prevention of the recurrence of stomach and duodenal ulcers:

- The recommended dose is 10 mg to 20 mg once a day. Your doctor may increase your dose to 40 mg once a day.

Treatment of stomach and duodenal ulcers caused by NSAIDs (non-steroidal anti-inflammatory drugs):

- The recommended dose is 20 mg once a day for 4-8 weeks.

Prevention of stomach and duodenal ulcers during administration of NSAIDs:

- The recommended dose is 20 mg once daily.

Treatment of **ulcers caused by *Helicobacter pylori*** infection and prevention of its recurrence:

- The recommended dose is 20 mg of omeprazol twice a day for one week.
- Your doctor will also instruct you to take two of the following antibiotics: amoxicillin, clarithromycin and metronidazole.

Treatment of excessive stomach acid produced by a **tumour in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you should take this medicine.

Use in children and adolescents

Treatment of the symptoms of GERD, such as **heartburn and acid regurgitation**

- Children over 1 year of age who weigh more than 10 kg can take omeprazol.

The dose for children is based on body weight, and your doctor will determine the correct dose.

Treatment of **ulcers caused by *Helicobacter pylori*** infection and prevention of its recurrence:

- Children over 4 years of age can take omeprazol. The dose for children is based on body weight, and your doctor will determine the correct dose.
- The doctor will also prescribe for your child two antibiotics, amoxicillin and clarithromycin.

How to take this medicine

- Taking the capsules in the morning is recommended.
- You may take your capsules with food or on an empty stomach.
- Swallow the capsules whole with half a glass of water. Do not chew or crush the capsules, as they contain coated granules that prevent the medicine from breaking down from the action of stomach acid. It is therefore important not to damage the granules.

What to do if you or your child has problems swallowing capsules

- If you or your child has problems swallowing capsules:
 - Open the capsules and swallow the contents directly with half a glass of water or pour the contents into a glass of still water, an acid fruit juice (e.g. apple, orange or pineapple) or apple sauce.
 - Always shake the mixture just before drinking (the mixture will not be transparent). Then drink the mixture immediately or within 30 minutes.
 - To make sure that you have taken all of the medicine, fill the glass of water halfway, swirl it thoroughly and drink all of the water. The solid parts contain the medicine; do not chew or crush them.

If you take more omeprazol cinfamed than you should

If you have taken more omeprazol than prescribed by your doctor, talk to your doctor or pharmacist immediately.

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately, indicating the medicine and the quantity ingested.

If you forget to take omeprazol cinfamed

If you forget to take a dose, take it as soon you remember. However, if it is almost time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking omeprazol cinfamed

Do not stop taking omeprazol without talking to your doctor or pharmacist first. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) but serious side effects, stop taking omeprazol and consult a doctor immediately:

- Sudden wheezing (sudden wheezing), swelling of the lips, tongue and throat or body, skin rash, fainting or difficulty swallowing (severe allergic reaction) (rare).
- Reddening of the skin with the formation blisters or peeling. Severe blisters and bleeding of the lips, eyes, mouth, nose and genitals may also appear. This could be “Stevens-Johnson syndrome” or “toxic epidermal necrolysis” (very rare).
- Generalised erythema, elevated body temperature and inflammation of the lymph nodes (DRESS or drug-induced hypersensitivity syndrome) (rare).
- A red, scaly, generalised rash with bumps under the skin and blisters that is accompanied by fever. The symptoms usually appear at the start of treatment (acute generalised exanthematous pustulosis) (rare).
- Yellowing of the skin, dark urine and tiredness, which can be symptoms of liver problems (rare).

Other side effects include:

Common side effects (may affect up to 1 in 10 people)

- Headache.
- Effects on the stomach or the intestine: diarrhoea, stomach ache, constipation and wind (flatulence).
- Nausea or vomiting.
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)

- Swollen feet and ankles.
- Sleep disturbances (insomnia).
- Dizziness, tingling sensation, drowsiness.
- Feeling that everything is spinning (vertigo).
- Changes in blood tests for checking liver function.
- Skin rash, welts and itching.
- General feeling of malaise and lack of energy.

Rare side effects (may affect up to 1 in 1,000 people)

- Problems in the blood, such as a reduction in white blood cells or platelets. This can cause weakness or bruising and increase the likelihood of contracting infections.
- Low concentration of sodium in the blood. This can cause weakness, vomiting and cramps.
- Agitation, confusion or depression.
- Taste alterations.
- Visual impairment, such as blurred vision.
- Sudden sensation of shortness of breath (bronchospasm).
- Dry mouth.
- Inflammation inside the mouth.
- Infection called “thrush” which can affect the intestine and is caused by a fungus.
- Hair loss (alopecia).
- Skin rash with exposure to sunlight.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Serious kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people)

- Alterations to blood count, such as agranulocytosis (lack of white blood cells).
- Aggressiveness.
- Seeing, feeling or hearing things that do not exist (hallucinations).
- Severe liver problems that cause liver failure and inflammation of the brain.
- Erythema multiforme.
- Muscle weakness.
- Increased breast size in males.

Not known (frequency cannot be estimated from the available data)

- Inflammation in the intestine (which causes diarrhoea).
- If you are taking omeprazol for more than three months, your blood magnesium levels may decrease. Low magnesium levels can manifest as fatigue, involuntary muscle contractions, disorientation, seizures, dizziness or increased heart rate. If you have any of these symptoms, tell your doctor immediately. Low magnesium levels can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to carry out regular tests to monitor your magnesium levels.
- Rash, possibly with joint pain.

In very rare cases, omeprazol can affect the white blood cells and cause immunodeficiency. If you suffer from an infection with symptoms, such as a fever with a very poor overall condition, or fever with symptoms of a local infection, such as pain in your neck, throat or mouth or difficulty urinating, you should consult your doctor as soon as possible to have a blood test and be able to rule out a lack of white blood cells (agranulocytosis). It is important at that moment for you to provide information about the medicine you are taking.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store omeprazol cinfamed

Keep this medicine out of the sight and reach of children.

Blister: Do not store at a temperature above 25°C. Store in the outer packaging to protect it from humidity.

Bottle: Keep the bottle tightly closed to protect it from moisture.

Do not use this medicine after the expiry date which is stated on the packaging, bottle label or on the blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What omeprazol cinfamed contains

- The active substance is omeprazole. Each hard capsule contains 20 mg of omeprazole.
- The other ingredients are:
 - Capsule contents:** sugar spheres (sucrose, corn starch and purified water), magnesium hydroxide and corn starch, sodium lauryl sulphate, anhydrous disodium hydrogen phosphate, mannitol (E-421), hypromellose, macrogol 6000, talc, polysorbate 80, titanium dioxide (E-171), methacrylic acid and ethyl acrylate copolymer (1:1) dispersion 30% and sodium carboxymethyl starch type A (from potato).
 - Capsule coating:**
 - Cap: titanium dioxide (E-171) and gelatine.
 - Body: black iron oxide (E-172), titanium dioxide (E-171) and gelatine.

What omeprazol cinfamed looks like and contents of the pack

Hard gelatine capsules, with a blue cap and white body, containing white to cream-white microgranules.

Aluminium/aluminium blister pack. Each pack contains 14, 28, 56 or 500 (clinical pack) capsules.

HDPE bottle with screw cap and desiccant capsule. Each pack contains 14, 28 or 56 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

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莎華 - 「健胃加」20毫克耐胃液硬膠囊

使用此藥物前請細心閱讀此說明書全部內容, 因為其中包含對您有用的重要信息。竹

- 請保留此說明書，以便可以再次翻閱。
- 如有任何問題，請向您的醫生或藥劑師商討。
- 此藥只處方給你，請勿給其他人使用，即使對方病徵跟你相似也可能造成傷害。
- 如有任何副作用，請向您的醫生或藥劑師商討，這包括本說明書中未有列出的任何可能的副作用。請參閱第4節。

這張說明書內包含甚麼資料？

1. 莎華 - 「健胃加」是甚麼及用於甚麼情況
2. 服用莎華 - 「健胃加」前, 您需要知道甚麼
3. 如何服用莎華 - 「健胃加」
4. 可能的副作用
5. 如何貯存莎華 - 「健胃加」
6. 包裝及其他資料

1. 莎華 - 「健胃加」是什麼以及它的用途？

莎華 - 「健胃加」含有活性成分奧美拉唑(omeprazole)。它屬於一組被稱為「質子泵抑制劑」的藥物。這些藥物的作用是減少胃酸產生的胃酸量。

莎華 - 「健胃加」用於治療以下疾病：

在成年人中：

- 「胃食道逆流疾病」(GERD)。當胃酸進入食道（連接喉嚨和胃的管道）時，就會發生這種情況，導致疼痛、炎症和燒灼感。
- 腸道上部（十二指腸潰瘍）或胃部（胃潰瘍）的潰瘍。
- 被稱為「幽門螺旋桿菌」的細菌感染的潰瘍。如果您患有這種疾病，您的醫生因此會處方抗生素來治療這感染並讓潰瘍癒合。
- 潰瘍是因為類稱為非類固醇消炎藥 (NSAID) 的藥物引起。如果您正在服用非類固醇消炎藥 (NSAID)，莎華 - 「健胃加」也可用於預防潰瘍的形成。
- 胰腺腫瘤產生過多的胃酸（柔林格綜合症） Zollinger-Ellison syndrome)

在兒童中：

- 1歲以上且體重≥10公斤的兒童
- 「胃食道逆流疾病」(GERD)。當胃酸進入食道（連接喉嚨和胃的管道）時，就會發生這種情況，導致疼痛、炎症和燒灼感。在兒童中，該疾病的症狀可能包括胃內容物返回口腔（反流）、嘔吐和體重增加不足。

4歲以上的兒童和青少年

- 被稱為「幽門螺旋桿菌」的細菌感染的潰瘍。如果您的孩子患有這種疾病，您的醫生可能會處方抗生素來治療這感染並讓潰瘍癒合。

2. 服用莎華 - 「健胃加」之前, 您需要知道甚麼

不要服用莎華 - 「健胃加」

- 如果您對奧美拉唑或此該藥物的任何其他成分過敏（列於第 6 節）

- 如果您對含有質子泵抑制劑的藥物（例如泮托拉唑、蘭索拉唑、雷貝拉唑或埃索美拉唑）過敏。
- 如果您正在服用含有奈非那韋（用於治療 HIV 感染）的藥物。

如果您屬於上述任何一種類別，請勿服用莎華 - 「健胃加」。如果您不確定屬於那一種類別，在服用莎華 - 「健胃加」之前，請向您的醫生或藥劑師商討。

警告和注意事項

在開始服用莎華 - 「健胃加」之前，請向您的醫生或藥劑師商討。

嚴重皮膚不良反應包括史蒂芬森強症候群（Stevens-Johnson syndrome）、毒性表皮溶解症、藥物反應伴嗜酸性粒細胞增多和全身症狀 (DRESS) 以及急性全身性發疹性膿疱病 (AGEP) 已有關於莎華 - 「健胃加」治療的報導。有報導。如果您出現與第 4 節所述的嚴重皮膚反應相關的任何症狀，請停止服用莎華 - 「健胃加」並立即就醫。

莎華 - 「健胃加」可能掩蓋其他疾病的症狀。如果您在開始服用莎華 - 「健胃加」之前或治療期間遇到以下任何情況，請立即諮詢您的醫生：

- 您的體重無緣無故減輕以及有吞嚥困難。
- 您有胃痛或消化不良。
- 您出現嘔吐食物或血液。
- 您的大便是黑色的（糞便沾有血跡）。
- 如果您有嚴重或持續的腹瀉，及有稍微增加感染性腹瀉是與奧美拉唑有關。
- 你有嚴重的肝臟問題。
- 如果您在服用其他類似莎華 - 「健胃加」的藥物治療以降低胃酸度後出現皮膚反應。
- 在服用這種藥物之前，請告訴您的醫生您是否計劃進行特定的血液檢查（嗜鈣粒蛋白 A）。

如果您長期（超過 1 年）服用莎華 - 「健胃加」，您的醫生可能會進行定期檢查。每當您去看醫生時，您都應該報告任何新的或不尋常的症狀或情況。

如果您服用莎華 - 「健胃加」等質子泵抑制劑，髖部、腕部或脊柱骨折的風險可能會略有增加，尤其是服用時間超過一年時。如果您患有骨質疏鬆症或正在服用皮質類固醇（這會增加骨質疏鬆症的風險），請告知您的醫生。

如果您出現皮膚，尤其是在暴露在陽光下的皮膚部位，請盡快與您的醫生聯繫，因為可能需要停止莎華 - 「健胃加」治療。請記住捉及您可能注意到的任何其他症狀，例如關節痛。

當服用奧美拉唑時，腎臟可能會出現故障。病徵和症狀可能包括尿量減少或尿中帶血或過敏反應，例如發燒、皮疹和關節僵硬。您應該向治療您的醫生報告這些徵狀。

兒童

一些患有慢性疾病的兒童及需要長期治療者，不建議服用。不要給 1 歲以下或體重小於 10 公斤的兒童服用此藥。

服用莎華 - 「健胃加」與其他藥物

請告知您的醫生或藥劑師，如果您正在服用、最近服用或可能需要服用任何其他藥物，這包括非處方藥物。因為奧美拉唑(omeprazole)可能影響一些藥物的作用機制，而一些藥物亦可能影響奧美拉唑(omeprazole)。

如果您正在服用含有奈非那韋（用於治療 HIV 感染）的藥物，請勿服用莎華 - 「健胃加」。

- 如果您正在服用以下任何一種藥物，請告知您的醫生或藥劑師：
 - 西咪替丁（由曲康唑、泊沙康唑或伏立康唑（用於治療真菌感染）。
 - 地高辛（用於治療心臟問題）。
 - 地西泮（用於治療焦慮症，作為肌肉鬆弛劑或癲癇症）。
 - 苯妥英（用於癲癇）。如果您正在服用苯妥英，當您開始或結束莎華 - 「健胃加」治療時，您的醫生將會對您進行監測。
 - 用於預防血栓的藥物，如華法林或其他維他命 K 拮抗劑。當您開始或結束莎華 - 「健胃加」治療時，您的醫生將會對您進行監測。
 - 利福平（用於治療結核病）。
 - 阿扎那韋（用於治療 HIV 感染）。
 - 他克莫司（在器官移植的情況下服用）。
 - 聖約翰草（貫葉連翹）（用於治療輕度抑鬱症）。
 - 西洛他唑（用於治療間歇性跛行）。
 - 沙奎那韋（用於治療 HIV 感染）。
 - 氣吡格倫（用於預防血栓（血栓形成））。
 - 厄洛替尼（用於治療癌症）。
 - 甲氨蝶呤（用於治療癌症的高劑量化療藥物）- 如果您正在使用高劑量的甲氨蝶呤，您的醫生將暫時停止使用莎華 - 「健胃加」進行治療。

如果除了莎華 - 「健胃加」外，您的醫生還給您處方了抗生素阿莫西林和克拉釐素來治療幽門螺旋桿菌感染引起的潰瘍，請務必告知您的醫生您正在服用的其他藥物。

隨食物和飲料服用莎華 - 「健胃加」

您可以隨食物服用您的膠囊或空腹服用。見第 3 節。

懷孕和哺乳期

如果您正懷孕或哺乳，懷疑您可能懷孕或打算懷孕，請在服用此藥前諮詢您的醫生或藥劑師。

莎華 - 「健胃加」會進入母乳，但當以治療劑量使用時不太可能影響兒童。

如果您是母乳喂養，您的醫生將決定您是否可以服用莎華 - 「健胃加」。

駕駛和使用機器

莎華 - 「健胃加」不大可能影響您駕駛或使用機器或工具的能力。可能會出現頭暈和視覺障礙等副作用（見第 4 節）。如果發生這種情況，您不應駕駛或操作機器。

莎華 - 「健胃加」含有蔗糖和鈉

這種藥物含有蔗糖。如果您的醫生告訴您對某些糖不耐受，請在服用此藥前諮詢您的醫生。

此藥物每劑量單位含有少於 1 毫摩爾鈉 (23 毫克)；也就是說，它基本上是「無鈉」的。

3. 如何服用莎華 - 「健胃加」

要完全按照醫生的指示服用。如果您不確定，請諮詢您的醫生或藥劑師。

您的醫生會指出您應該服用多少膠囊以及服用多長時間。這將取決於您的病情和年齡。

推薦劑量為：

使用於成人

治療胃食道逆流疾病 (GERD) 的症狀，例如胃灼熱和胃酸倒流：

- 如果您的醫生發現您的食道有輕微損傷，建議劑量為 20 毫克，每天1次，持續 4-8 週。如果您的食道尚未癒合，您的醫生可能會再處方 8 週的 40 毫克劑量。
- 食道癒合後的推薦劑量為每天 10 毫克。
- 如果您的食道沒有受損，建議劑量為每天 10 毫克。

治療腸道上部潰瘍（十二指腸潰瘍）：

- 推薦劑量為 20 毫克，每天2次，持續 2 週。如果潰瘍尚未癒合，您的醫生可能會再處方 2 週的相同劑量。
- 如果潰瘍沒有完全癒合，劑量可以增加到 40 毫克，每天1次，持續 4 週。

治療胃潰瘍（胃潰瘍）：

- 推薦劑量為 20 毫克，每天 1 次，持續 4 週。如果潰瘍尚未癒合，您的醫生可能會再處方同樣的劑量 4 週。
- 如果潰瘍沒有完全癒合，劑量可以增加到 40 毫克，每天1次，續 8 週。

預防胃和十二指腸潰瘍復發：

- 推薦劑量為 10 毫克至 20 毫克，每天1次。您的醫生可能會將您的劑量增加到每天 40 毫克。

治療由非類固醇消炎藥 (NSAID) 引起的胃和十二指腸潰瘍：

- 推薦劑量為 20 毫克，每天1次，持續 4-8 週。

服用非類固醇消炎藥 期間預防胃和十二指腸潰瘍：

- 推薦劑量為每天 20 毫克。

治療幽門螺旋桿菌感染引起的潰瘍並預防復發：

- 通常的劑量是 20 毫克莎華 - 「健胃加」，每天 2 次，持續 1 週。
- 您的醫生還會指導您服用以下兩種抗生素：阿莫西林、克拉釐素和甲硝唑。

治療胰腺腫瘤產生的過量胃酸 (柔林格綜合症 Zollinger-Ellison syndrome)：

- 推薦劑量為每天 60 毫克。
- 您的醫生會根據您的需要調整劑量，並會決定您應該服用該藥多長時間。

用於兒童和青少年

治療胃食道逆流疾病的症狀，如胃灼熱和胃酸倒流

- 1 歲以上體重超過 10 公斤的兒童可以服用莎華 - 「健胃加」。兒童的劑量基於體重，您的醫生將決定正確的劑量。

治療幽門螺旋桿菌感染引起的潰瘍並預防復發：

- 4 歲以上的兒童可以服用莎華 - 「健胃加」。兒童的劑量基於體重，您的醫生將決定正確的劑量。
- 醫生還會為您的孩子處方兩種抗生素，阿莫西林和克拉釐素。

如何服用此藥

- 建議在早上服用膠囊。
- 您可以隨食物或空腹服用膠囊。
- 用半杯水將膠囊整個吞下。不要咀嚼或壓碎膠囊，因為它們含有包衣顆粒，可防止藥物因胃酸的作用而分解。因此，重要的是不要損壞顆粒。

如果您或您的孩子吞嚥膠囊有問題應該怎麼處理

- 如果您或您的孩子吞嚥膠囊有問題：
 - 打開膠囊，直接用半杯水吞服內容物，或將內容物倒入一杯水中、酸性果汁（例如蘋果汁或菠蘿）或蘋果醬中。
 - 飲用前一定要搖勻（混合物不會透明）。然後立即或在 30 分鐘內飲用混合物。
 - 為確保您已服用完所有藥物，請將一杯水倒入一半，然後徹底搖晃並喝掉所有的水。固體部分含有藥物；不要咀嚼或壓碎它們。

如果您服用的莎華 - 「健胃加」多於您應該服用份量

如果您服用的莎華 - 「健胃加」多於醫生的處方，請立即與您的醫生或藥劑師商討。

如果服用過量或意外攝入，請立即諮詢您的醫生或藥劑師，並說明服用的藥物和數量。

如果您忘記服用莎華 - 「健胃加」

如果您忘記服用一劑，請在想起來後儘快服用。但是，如果幾乎是下一次服藥的時間，請跳過忘記的劑量。不要服用雙倍劑量來彌補忘記的劑量。

如果您停止服用莎華 - 「健胃加」

在沒有與您的醫生或藥劑師溝通的情況下，請勿停止服用莎華 - 「健胃加」。如果您對使用此藥有任何進一步的問題，請諮詢您的醫生或藥劑師。

4. 可能的副作用

像所有藥物一樣，這種藥物亦可能會引起副作用，儘管不是每個人都會得到。

如果您發現以下任何罕見 (可能影響多達千分之一的人) 或非常罕見 (可能影響多達萬分之一的人) 但嚴重的副作用，請停止服用莎華 - 「健胃加」並立即諮詢您的醫生：

- 突然喘息（突然氣喘）、嘴唇、舌頭和喉嚨或身體腫脹、皮疹、昏厥或吞嚥困難（嚴重的過敏反應）（罕見）。
- 皮膚變紅形成水泡或脫皮。嘴唇、眼睛、口腔、鼻子和生殖器也可能出現嚴重的水泡和出血。這可能是「史蒂芬斯-約翰遜綜合症」或「中毒性表皮溶解症（非常罕見）。
- 廣泛性紅斑、體溫升高和淋巴結炎症 (DRESS 或藥物引起的超敏反應綜合徵)（罕見）。
- 紅色、鱗片、全身性皮膚連皮下有腫塊，以及水泡伴有發燒。這些症狀通常出現在治療開始時（急性廣泛性發疹性膿疱病）（罕見）。
- 皮膚發黃、尿液變黑和疲倦，這可能是肝臟問題的症狀。

其他副作用包括：

常見副作用 (可能影響多達 10 人中的 1 人)

- 頭痛。
- 對胃或腸道的影響：腹瀉、胃痛、便秘和風（脹氣）。
- 噁心或嘔吐。
- 胃中的良性息肉。

不常見的副作用 (可能影響多達 100 人中的 1 人)

- 腳和腳踝腫脹。
- 睡眠障礙（失眠）。
- 頭暈、刺痛感、困倦。
- 感覺一切都在旋轉（眩暈）。
- 檢查肝功能的血液檢查變化。
- 皮疹、傷口和瘙癢。
- 全身不適和缺乏活能量。

罕見的副作用 (可能影響多達 1000 人中的 1 人)

- 血液問題，例如白細胞或血小板減少。這會導致虛弱或瘀傷，並增加感染的可能性。
- 血液中鈉濃度低。這會導致虛弱、嘔吐和痙攣。
- 激動、困惑或沮喪。
- 口味改變。
- 視力障礙，例如視力模糊。
- 突然感覺呼吸急促（支氣管痙攣）。
- 口乾。
- 口腔內發炎。
- 稱為「攝口瘡」的感染，可影響腸道，由真菌引起。
- 脫髮（脫髮）。
- 暴露在陽光下的皮疹。
- 關節痛（關節痛）或肌肉痛（肌痛）。
- 嚴重的腎臟問題（間質性腎炎）。
- 出汗增多。

非常罕見的副作用 (可能影響多達 10,000 人中的 1 人)

- 血細胞計數改變，例如粒細胞缺乏症（缺乏白細胞）。
- 攻擊性。
- 看到、感覺到或聽到不存在的事物（幻覺）。
- 導致肝功能衰竭的嚴重肝臟問題和大腦炎症。
- 肌肉無力。
- 男性乳房增大。

未知 (無法從可用數據估計頻率)。

- 腸道炎症（導致腹瀉）。
- 如果您服用莎華 - 「健胃加」超過三個月，您血液中的鎂含量可能會下降。低鎂水平可能出現疲倦、不自主的肌肉痙攣、定向障礙、癲癇發作、頭暈或心率加快。如果您有任何這些症狀，請立即通知您的醫生。低鎂水平也可能導致血液中的鉀和鈣水平下降。您的醫生可能會決定，定期進行血液檢查以監測您的鎂含量。
- 皮疹，可能伴有關節痛。

在極少數情況下，莎華 - 「健胃加」可能會影響白血球細胞並引發免疫缺陷。如果您出現感染症狀，例如發燒且整體狀況非常差，或發燒並伴有局部感染症狀，例如頭部、喉嚨或口腔疼痛或排尿困難，應盡快諮詢醫生並進行血液檢查及能夠避免缺乏白血球細胞出現（粒細胞缺乏症）。此時重要的是您提供有關您正在服用的藥物的資料。

報告副作用

如果您遇到任何副作用，請與您的醫生或藥劑師商討。這包括本說明書中未列出的任何可能的副作用。通過報告副作用，您可以幫助提供有關該藥物安全性的更多資料。

5. 如何貯存莎華 - 「健胃加」

請將本藥物存放於兒童視線範圍以外及不能觸及的地方。

鋁泡罩：請勿在高於 25°C 的溫度下存放。存放在外包裝中以防受潮。

瓶子：保持瓶子緊閉以防受潮。

請勿在包裝、瓶身標籤或鋁泡罩上“EXP”後註明的有效期後使用本藥。有效期是指指定月份的最後一天。

請勿通過廢水或生活垃圾丟棄任何藥物。詢問藥劑師如何丟棄不再使用的藥物。這些措施將有助於保護環境。

6. 包裝及其他資料

莎華 - 「健胃加」包含什麼：

- 主要成份是奧美拉唑(omeprazole)。
- 其他成分（賦形劑）是：
- 膠囊內容物：sugar spheres (sucrose and corn starch purified water), magnesium hydroxide and corn starch, sodium lauryl sulphate, anhydrous disodium hydrogen phosphate, mannitol (E-421), hypromellose, macrogol 6000, talc, polysorbate 80, titanium dioxide (E-171), methacrylic acid and ethyl acrylate copolymer (1:1) dispersion 30% and sodium carboxymethyl starch type A (from potato)。
- 硬明膠膠囊：明膠膠囊由 titanium dioxide (E-171)及 gelatine 製成。明膠膠囊丸身由：black iron oxide (E-172), titanium dioxide (E-171) 及 gelatine 製成

莎華 - 「健胃加」產品外觀和包裝內容:

硬明膠膠囊，藍色帽子和白色身體，含有白色至乳白色顆粒。

鋁鋁泡罩包裝：每包含 14、28、56 或 500（臨床包裝）粒膠囊。

鋁螺旋蓋和乾燥膜膠囊的 HDPE 瓶。每瓶含 14、28 或 56 粒膠囊。

並非所有包裝都有供應。

營銷持有人及製造商

營銷持有人

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Poligono Industrial Areta
31620, Huarte (Navarra) – Spain (西班牙)

製造商

Laboratorios Cinfa, S.A.
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或

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