在用這種藥物治療期間,不應飲用含酒精的飲料, 因爲這可能會增加副作用的風險。

- 視野模糊

- 體液滯留

髓的膜發炎 眼睛不適或發炎

- 血管發炎,高血壓

- 女性生育力下降

副作用報告

性的更多信息。

助保護環境。

6. 包裝及其他資料

and talc (E-553b).

製造商及營銷持有人

HK Reg. No. HK-52980

說明書最新修訂時間:2021年4月

莎華 - 「炎痛消」的外觀和包裝

- 實驗室檢查改變,體重減輕

5. 如何貯存莎華 - 「炎痛消」

請貯存於攝氏25度以下。

莎華 - 「炎痛消」包含什麼:

- 聽力問題

非常罕見:每10000人中有1人可能會受影響-- 史蒂文斯-約翰遜綜合症,中毒性表皮壞死,指甲 脫落,對光過敏的皮膚反應,皮疹或水皰形成的

- 由於紅血球細胞形成失敗或過早破壞而導致的紅

- 嚴重的過敏反應影響全身(過敏反應),皮疹伴 發燒,淋巴結腫大和關節痛(血清病)

- 抑鬱,睡眠障礙,幻覺,失眠,神智不清,情緒變化,躁動不安 - 因病毒,四肢麻木或刺痛感引起的覆蓋大腦和脊

支氣管痙攣阻塞空氣進入肺部,呼吸困難,流鼻

·對栓劑有疼痛,灼熱感,肛門直腸部位瘙癢或迫

切需要排便的反應,伴有絞痛,在極少數情況下 會因直腸出血,胃粘膜發炎,胃腸道出血包括由

於嘔吐而伴有血液或黑色大便引起出血,胰腺炎

於嘔吐川汁胃肌像效素已入医刀爬山肌 原原系 症,陽壁傷口或穿孔 - 致命的肝臟炎症,皮膚和粘膜發黃 - 脫髮,可能會致命的嚴重皮膚反應(剝脫性皮 炎,多形性紅斑,非血小板減少性紫癜) - 腎臟問題,例如腎病綜合症和間質性腎小球腎炎

(通常表現爲腎臟發炎和尿液蛋白流失)和腎衰

- 固定的藥疹(可能出現爲圓形或橢圓形斑塊,並 有皮膚發紅和腫脹,水疱(蕁麻疹),瘙癢

如果你有任何副作用,請諮詢你的醫生或藥劑師。這包括本說明書中未有列出的任何可能的副作用。 通過報告副作用,你可以幫助提供有關該藥物安全

請將藥物存放於兒童不能觸及和視線範圍以外。

用此藥物,有效期所指的是每個月最後一日。

在標籤和紙盒上註明的有效期後(月/年)切勿使

請勿丟棄任何藥物於污水及家居垃圾中,請向你的 藥劑師查詢如何棄置不再使用的藥物,這項措施有

- 主要成份是匹洛西卡(piroxicam)。每粒含有 20 毫克匹洛西卡(piroxicam)。

- 其他成份包括: microcrystalline cellulose (E-460),

calcium hydrogen phosphate dihydrate, maize

starch, sodium carboxymethyl starch, sodium

stearyl fumarate, magnesium stearate (E-470b)

莎華 - 「炎痛消」以長方形,雙凸,黃白色可分散 片形式提供,一側刻有痕跡,另一側標有"P20C" 。藥品以 PVC-PVDC/鉛泡罩形式提供。 每盒裝有

Laboratorios Cinfa, S.A. C/Olaz-Chipi, 10. Polígono Industrial Areta 31620 Huarte - Pamplona (Navarra) - SPAIN

香港威非路道 18 號萬國寶通中心 30 樓 3001 室 電話: 2470 1927 傳真: 2470 3448

未知:無法從可用數據中估算頻率

#### 懷孕及哺乳期婦女

懷孕及哺乳期婦女 如果您處於懷孕期最後 3 個月,請勿服用莎華 - 「 炎痛消」,因爲它可能會傷害未出生的嬰兒或在分 始過程中引起問題。 它可能會影響您和您時現 現腎臟和心臟問題。 它可能會影響您和您時間。 有出血傾向,並導致分娩比預期稍遲或較長加先 時間,並導致分娩比預期,等藥物會增加先天性畸形/流產或羊水流失的風險,因此不建議至 學的第一和和第二期服用此藥,除非認為不經對上 學的第一和和第二期服用此藥,除非認為不經對 是經你的醫生懷孕期間需要治療,則量和接續,如 主是經你可嘗試懷契到歸少。於數天,可能會導於致痛消,多於數天,可能會學水未 出生嬰兒有腎臟問題,分所導致嬰兒問圍等內 與服用莎華 - 「炎痛消,從而導致嬰兒問圍等內 與服用莎華 - 「炎痛消,從而導致嬰兒問圍等的治療 對大生 消」可能會降低生育能力。

對於生育年齡的婦女,必須考慮到使用莎華 - 「炎痛消」可能會降低生育能力。

告訴你的醫生你是否正在母乳喂養或即將開始母乳 喂養。 不建議在哺乳期使用莎華 - 「炎痛消」,因 爲在這種情況下尚未確定其臨床安全性。

#### 駕駛及操作機器

無數及珠 F 域的 如果在服用莎華 - 「炎痛消」的期間出現頭暈,眩暈,視力障礙或困倦,在這些症狀消退前或你清楚對本藥之耐受性前,請勿駕駛或操作危險機器。

匹洛西卡 (piroxicam) 含有鈉。這種藥物每片含有少於23毫克(1毫莫爾)的鈉;它基本上是"無鈉的"。

#### 3. 如何使用莎華 - 「炎痛消」

請遵照醫生或藥劑師的指示使用莎華 - 「炎痛消」 。如有疑問,請諮詢你的醫生或藥劑師。

莎華 - 「炎痛消」水溶片可用開水整粒吞服或可溶於一杯水中飲用。

你的醫生需定期爲你檢查,以確保你服用正確劑量的莎華 - 「炎痛消」。你的醫生會將你的治療調整到最低劑量以便能更有效控制你的症狀。在任何情 況下,如果未知會醫生,你不應該改變劑量。

你的醫生可能會處方莎華 - 「炎痛消」的同時再開另一種藥物以保護你的胃和腸兒受潛在的不良反應。

不要增加劑量。

如果你覺得這種藥不是很有效,請告訴你的醫生。 成人和長者:

每日匹洛西卡 (piroxicam) 最大劑量是 20 毫克作為單一劑量。

如果你超過70歲,你的醫生可能會處方較低的每 日劑量並縮短治療時間。

用於兒童:

不建議用於兒童上。

### 假如使用莎華 - 「炎痛消」多於你應使用份量

立即聯絡你的醫生,藥劑師或醫院急診科。

如果過量或意外攝入,請立即告知你的醫生或藥劑師,並註明藥物和攝入量。

### 假如你忘記使用莎華 - 「炎痛消」

當記起時盡快服用。 如果快到下一次服藥的時間,請不要服用你錯過的劑量,而是要等下一次服 不要服用雙倍劑量來彌補被遺忘的劑量。

如果你對該藥物的使用還有其他疑問,請諮詢你的 醫生或藥劑師。

#### 4. 可能的副作用

像其他藥物一樣,此藥物可能會引起副作用,儘管並不是所有人都會有此情況,匹洛西卡 (piroxicam)通常具有良好的耐受性。

匹洛西卡 (piroxicam) 的副作用因人而異,但通常 是輕微且短暫的。

以下列表將列出各項副作用,如果你發現任何不 適,請告知醫生。

常見:每10人中有1人可能會受影響

- 吊兒:與10人中旬1人可能曾受蒙譽
   血液中的紅血球,白血球和血小板減少;某些白血球升高(嗜酸性粒細胞增多)
   食慾不振,血糖水平升高
   頭暈,頭痛,嗜睡,眩暈
   耳朵裡嗡嗡作響的聲音
   腹部疼痛或不適,便秘,腹瀉,上腹部不適,腸胃氣脹,噁心,嘔吐,消化不良

- 皮膚瘙癢,皮疹
   腳踝腫脹(水腫)
   可逆轉的尿素氮 (BUN) 升高或肝酶(轉氨酶)升高,可能會影響某些醫學檢查,體重增加
- 不常見:每100人中有1人可能會受影響
- 心悸 牙齦發炎

#### - 可逆轉的肌酸酐升高會影響某些醫學檢查 - 史蒂文斯-約翰遜綜合症,中毒性表皮壞死,指甲 脫落,對光過敏的皮膚反應,皮疹或水皰形成的 piroxicam cinfa 20 mg dispersible tablets

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

Package leaflet: Information for the user

- Keep this leaflet. You may need to read it again.
   If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
   If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed
- in this leaflet. See section 4.

#### What is in this leaflet

- What piroxicam cinfa is and what it is used for
   What you need to know before you take piroxicam cinfa
- How to take piroxicam cinfa
   Possible side effects
- 5. How to store piroxicam cinfa
- 6. Contents of the pack and other information

#### 1. What piroxicam cinfa is and what it is used for

piroxicam cinfa is an antiinflammatory medicine that belongs to the group of medicines called nonsteroidal antiinflammatory drugs (NSAIDs).

piroxicam cinfa is used to relieve some symptoms caused by osteoarthrosis (degenerative joint disease), rheumatoid arthritis and ankylosing spondylitis (rheumatism of the spine), such as swelling, stiffness and pain of the joints. It does not cure osteoarthritis, but it helps relieve some symptoms only as large as you continue to take it. symptoms only as long as you continue to take it.

Before prescribing piroxicam, your doctor must assess the benefits of this medicine in relation to the risk of developing adverse reactions. Due to treatment with piroxicam, you may need to have regular checks; your doctor will tell you how often these will be.

Your doctor will only prescribe piroxicam to you when other nonsteroidal antiinflammatory drugs (NSAIDs) have not relieved your symptoms.

# 2. What you need to know before you take piroxicam cinfa Do not take piroxicam cinfa

- If you are allergic to piroxicam or any of the other ingredients of this medicine (listed in section 6).
- you have had a stomach or intestinal ulcer, bleeding or perforation.
- or perforation.

   If you have a stomach or intestinal ulcer, bleeding or perforation.

   If you have or have previously had gastrointestinal disorders (inflammation of the stomach or intestine) that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, stomach or bowel cancer, or diverticulitis (inflammation or infection of the pouches/pockets in the colon) pockets in the colon).

  If you are taken
- pockets in the colon). If you are taking other nonsteroidal antiinflammatory drugs (NSAIDs), including selective COX-2 inhibitors and acetylsalicylic acid (aspirin), present in many medicines used to relieve pain and lower fever.
- If you are taking anticoagulants such as warfarin, coumarins or the new oral anticoagulants including apixaban, dabigatran and rivaroxaban, used to prevent
- If you have previously suffered a severe allergic reaction to piroxicam, other NSAIDs or other medicines, especially serious skin reactions (regardless of severity) especially serious skin reactions (regardless of severity) such as exfoliative dermatitis (intense reddening of the skin, with skin peeling off in scales or layers), blistering reactions (Stevens-Johnson syndrome, characterised by red blisters, erosion and crusty or bleeding skin) or toxic epidermal necrolysis (a disease with blistering and peeling of the superficial layers of the skin), or if you have experienced other allergic manifestations such as asthma attacks, severe need congestion or other allergic asthma attacks, severe nasal congestion or other allergic reactions such as itching of the skin, rash, swelling of the face, lips or tongue, causing breathing difficulties or wheezing in the chest.

  If you develop a rash or skin symptoms, stop taking
- piroxicam immediately, seek urgent medical advice and inform your doctor that you are taking this medicine.
- If you have acute liver or kidney disease.

- If you have severe heart failure.

  If you have blood clotting disorders.

  If you are in the last three months of pregnancy.

If any of these apply to you, do not take piroxicam. Tell your doctor immediately.

# Warnings and precautions

Talk to your doctor or pharmacist before taking piroxicam

<u>Gastrointestinal risks</u> In the same way as the rest of the nonsteroidal antiinflammatory drugs, piroxicam cinfa can cause severe reactions in the stomach and intestine, such as pain, bleeding, ulcers and perforation. The administration of doses of over 20 mg a day implies an increased risk of gastrointestinal side effects. Adverse effects can be minimised by using the lowest effective dose for the shortest possible time.

You should stop treatment with piroxicam and talk to your doctor if you have stomach pain or any sign of bleeding in the stomach or intestines, such as black or bloody stools or vomiting blood.

In the event of any new abdominal sign or symptom, or any gastrointestinal complication during treatment, suspend the medication and consult your doctor immediately.

<u>Skin risks</u>
There have been reports of skin rashes that may prove life-threatening (Stevens-Johnson syndrome and toxic epidermal necrolysis) when using piroxicam. These rashes initially appear as red spots or circular blotches, often with a blister at the centre.

Other signs that may appear include sores in the mouth, throat, nose, genitals and conjunctivitis (red and swollen

Potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to form widespread blisters or flaking of the skin.

The highest risk of the appearance of serious skin reactions is during the first few weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis when using piroxicam, you should not use the medication again at any time.

If you develop a rash or these skin symptoms, you should stop taking piroxicam, visit your doctor immediately and tell him/her that you are taking this medicine.

Cardiovascular and cerebrovascular risks
Medicines like piroxicam cinfa may be associated with
a moderate increase in the risk of suffering heart attack
("myocardial infarction") or stroke. This risk is more likely to occur when high doses and long-term treatments are used. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, a history of stroke or think you might be at risk of suffering these conditions (for instance, you have high blood pressure, diabetes, increased cholesterol, or are a smoker), ask your doctor or pharmacist about this treatment.

Furthermore, this type of medicine can cause fluid retention, particularly in patients with heart failure and/or high blood pressure (hypertension).

# Other risks

If you are over the age of 70, your doctor may reduce the duration of the treatment and carry out checks more often while you are taking piroxicam.

If you are taking other medications such as corticosteroids or certain medicines for depression called selective serotonin reuptake inhibitors (SSRIs) or acetylsalicylic acid to prevent blood clots, your doctor may prescribe a medicine to protect your stomach or intestine together with piroxicam cinfa.

Do not take this medicine if you are over the age of 80.

If you have or have previously had any medical problem or any type of allergy or if you are not sure whether you can take piroxicam, talk to your doctor before using this

Make sure your doctor knows about all the medicines you are taking, including those obtained without a prescription.

You should also take piroxicam cinfa with caution and always following your doctor's instructions in the following situations:

- If you have moderate or mild kidney or liver disease.
- If you have severe dehydration.
  If you have an infection, as it could mask fever and mistakenly make you believe that you are better or that the infection is not serious.
- You should see an ophthalmologist if you have eye problems during treatment with piroxicam.
- If you suffer from asthma.If you are taking anticoagulants.

Other medicines and piroxicam cinfa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Certain medicines can interact with each other. Your doctor may limit your use of piroxicam and/or other medicines, or you may need to change to a different medicine. It is especially important to tell your doctor if you are taking

- any of the following medicines:

   Aspirin or other nonsteroidal antiinflammatory drugs to
  - relieve pain.
    Corticosteroids, which are medicines used to treat many diseases such as allergies, hormonal disorders and inflammatory diseases.

    Anticoagulants such as warfarin, coumarins or the
- new oral anticoagulants (apixaban, dabigatran and rivaroxaban) to prevent blood clots.
- Medicines for depression called selective serotonin reuptake inhibitors (SSRIs).
- Medicines to prevent platelet aggregation such as acetylsalicylic acid.

  Lithium (medicine used for bipolar depression).
- Methotrexate (medicine used in rheumatoid arthritis and to treat certain cancers).
- Ticlopidine (antiplatelet medicine).
- Quinolones (anti-infection medicines).
   Certain diuretics (medicines used to treat fluid retention). in high blood pressure). Sulfonylureas (oral antidiabetic medicines).
- Cyclosporine or tacrolimus (medicines used in transplant patients).





heart attack). Digoxin: concomitant treatment with digoxin and piroxicam does not affect the plasma levels of either of these drugs.

Talk to your doctor immediately in any of these situations.

#### piroxicam cinfa with food, drink and alcohol

. Taking piroxicam cinfa with food may cause a small delay in effect; administration between meals is therefore advised.

Alcoholic beverages should not be consumed during treatment with this medicine, as it may increase the risk of side effects.

Pregnancy and breast-feeding
Do not take piroxicam cinfa if you are in the last 3 months of pregnancy, as it may harm your unborn baby or cause problems during delivery. It may cause kidney and heart problems in your unborn baby. It may affect your and your baby's propensity to bleed and delay or lengthen delivery more than expected. Since the administration of medicines more than expected. Since the administration of medicines like piroxicam cinfa has been associated with an increased risk of congenital abnormalities/miscarriages or loss of amniotic fluid, its administration is not recommended during the first and second trimesters of pregnancy, unless tit is considered absolutely necessary and as instructed by your doctor. In these cases, if you need treatment during this period or while trying to become pregnant, the dose and duration should be limited as much as possible. After week 20 of pregnancy, the use of piroxicam cinfa may cause week 20 of plegiality, the use of photical children inly cause kidney problems in your unborn baby if taken for more than a few days, which may lead to low levels of amniotic fluid surrounding the baby (oligohydramnios) or narrowing of a blood vessel called the ductus arteriosus in the baby's heart. If you need treatment for more than a few days, your doctor may recommend additional monitoring.

Women of child-bearing age must take into account that medicines like piroxicam cinfa have been associated with reduced fertility.

Tell your doctor if you are breast-feeding or about to start breast-feeding. The use of piroxicam cinfa is not recommended during breast-feeding, since its clinical safety has not been established in this situation.

**Driving and using machines**If you notice any dizziness, vertigo, visual disturbances or drowsiness while taking piroxicam, do not drive or use dangerous machinery until these symptoms disappear or you know how you tolerate the medicine.

Piroxicam contains sodium. This medicine contains less than 23 mg (1 mmol) of sodium per tablet; it is essentially "sodium-free".

#### 3. How to take piroxicam cinfa

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

piroxicam cinfa dispersible tablets can be swallowed whole with a little liquid or can be dissolved in a glass of water.

Your doctor will give you regular check-ups to make sure you

are taking the right dose of piroxicam.

Your doctor will adjust your treatment to the lowest dose that best controls your symptoms. Under no circumstances should you change your dose without speaking to your doctor first.

Your doctor may prescribe piroxicam with another medicine to protect your stomach and intestines from potential adverse reactions.

Do not increase the dose.

If you feel that the medicine is not very effective, talk to vour doctor.

Adults and elderly patients: The maximum daily dose is 20 mg of piroxicam taken as a single daily dose.

If you are over the age of 70, your doctor may prescribe a lower daily dose and reduce the duration of treatment.

Use in children:

Its use in children is not recommended.

## If you take more piroxicam cinfa than you should

Immediately contact your doctor or pharmacist or emergency department of your hospital.

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

#### If you forget to take piroxicam cinfa

Take it as soon as you remember it. If it is almost time to take the next dose, do not take the one you missed and wait to take the next dose. Do not take a double dose to make up for a forgotten dose.

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. Piroxicam is generally well tolerated.

The side effects of piroxicam vary in intensity from one person to another but are generally mild and transient.

A list of side effects is given below. It is important that you tell your doctor if you notice any discomfort.

**Common:** may affect up to 1 in 10 people

- Reduced red blood cells, white blood cells and platelets in blood; elevation of certain white blood cells (eosinophilia).
- Loss of appetite, increased blood sugar levels.
- Dizziness, headache, drowsiness, vertigo.

- Buzzing sounds in the ears.
- Abdominal pain or discomfort, constipation, diarrhoea, upper abdominal discomfort, flatulence, nausea, vomiting, indigestion. Itching of the skin, rash

- Ankle swelling (oedema).
   Reversible blood urea nitrogen (BUN) elevation or increased liver enzymes (transaminases) that can affect some medical tests, weight gain.

#### Uncommon: may affect up to 1 in 100 people

- Palpitations. Inflamed gums.
- Reversible creatinine elevation that can affect some medical tests.
- Stevens-Johnson syndrome, toxic epidermal necrolysis, shedding of nails, skin reactions due to allergy to light, skin rash with formation of vesicles or blisters.
- Low blood sugar levels.
- Blurred vision.

Very rare: may affect up to 1 in 10,000 people
- Stevens-Johnson syndrome, toxic epidermal necrolysis, shedding of nails, skin reactions due to allergy to light, skin rash with formation of vesicles or blisters.

Not known: frequency cannot be estimated from the

- Reduced red blood cell counts due to failed red cell
- formation or premature destruction.

  Serious allergic reaction affecting the entire body (anaphylaxis), rash accompanied by fever, swelling of the lymph nodes and joint pain (serum sickness).
- Fluid retention.
- Depression, sleep disturbances, hallucinations, insomnia, confusion, mood changes, restlessness.

  Inflammation of the membranes covering the brain and spinal cord caused by viruses, numbness or tingling sensation of the extremities. Irritation or inflammation of the eyes.
- Hearing problems.
- Hearing problems.

  Blood vessel inflammation, high blood pressure.

  Bronchial spasms obstructing air passage into the lungs, breathing difficulty, nosebleed.

  Reaction to suppositories with pain, burning sensation,
- Reaction to suppositories with pain, burning sensation, itching in the anorectal zone or urgent need to defecate, accompanied by colic pain and in rare cases by rectal bleeding, inflammation of the gastric mucosa, gastrointestinal bleeding including vomiting with blood or dark stools due to bleeding, pancreatic inflammation, intestinal wall wounds or perforations.

  Fatal inflammation of the liver, yellowing of the skin and mucous membranes.
- mucous membranes.
- Hair loss, serious skin reactions that may prove fatal (exfoliative dermatitis, erythema multiforme, non-
- Kidney inflammation and protein loss in urine), and renal failuré.
- Decreased female fertility.
- Laboratory test alterations, weight loss,
- Fixed drug eruption (may appear as round or oval plaques with redness and swelling of the skin, blisters (urticarial), itching.

# 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 piroxicam cinfa

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

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

Do not store at temperatures above 25°C.

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 piroxicam cinfa contains

- The active substance is piroxicam. Each tablet contains 20 mg of piroxicam.

  The other ingredients are: microcrystalline cellulose (E-
- 460), calcium hydrogen phosphate dihydrate, maize starch, sodium carboxymethyl starch (type A)(potato), sodium stearyl fumarate, magnesium stearate (E-470b) and talc (E-553b).

#### What piroxicam cinfa looks like and contents of the pack

piroxicam cinfa is supplied as oblong, biconvex, white-yellow dispersible tablets scored on one side and marked with "P20C" on the other. The medicinal product is supplied in PVC-PVDC/Aluminium blisters. Each pack contains 20 tablets.

### Marketing Authorisation Holder and Manufacturer

Laboratorios Cinfa, S.A. Carretera Olaz-Chipi, 10. Polígono Industrial Areta 31620 Huarte (Navarre) - Spain

<u>Distributor</u> Reich Pharm Limited Unit 3001, 30/F, Citicorp Centre, 18 Whitfield Road - Hong Kong Tel.: 2470 1927 Fax: 2470 3448

Hk Reg. No. HK-52980

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# 說明書:使用者說明 莎華 - 「炎痛消」 20 毫克水溶片

# 此說明書含有重要資訊,使用此藥物前請細心閱讀此說明書全部內容。

- 請保留此說明書,以便可以再次翻閱。- 如有任何問題,請向你的醫生或藥劑師或護士查詢。- 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,請咨詢醫生或藥劑師或護士,此包括任何未有在此說明書列出的任何可能的副作用。

### 這張說明書內包含甚麼資料?

- 1. 莎華 「炎痛消」是甚麼及用於甚麼情況 2. 使用莎華 「炎痛消」前你需要留意甚麼 3. 如何使用莎華 「炎痛消」

- 4. 可能的副作用 5. 如何貯存莎華 「炎痛消」 6. 包裝及其他資料

### 1. 莎華 - 「炎痛消」是甚麼及用於甚麼情況

- 「炎痛消」屬於一種稱爲非類固醇抗炎藥 (NSAIDs) 的藥物。

莎華 - 「炎痛消」用於緩解由骨關節炎(退化性關節病),類風濕性關節炎和強直性脊椎炎(脊柱風濕病)引起的一些症狀,如腫脹,僵硬和關節疼痛。它不能治癒骨關節炎,但只要持續服用,則有助於緩解

在開始使用莎華 - 「炎痛消」之前,你的醫生必須評估相對於發生不良反應風險,使用本藥所獲得的益處。由於使用莎華 - 「炎痛消」治療,你可能需要定 期檢查;你的醫生會告訴你應隔多久需要檢查。

你的醫生只會在其他非類固醇抗炎藥 (NSAIDs) 未能 舒緩你的症狀時才處方莎華 - 「炎痛消」

#### 2. 使用莎華 -「炎痛消」前你需要留意甚麼? 請勿使用莎華 - 「炎痛消」假如你:

- 對此藥成份匹洛西卡 (piroxicam) 或其他任何成份 過敏(在第6部分列出)。 如果你患有胃或腸潰瘍,出血或穿孔。
- 如果你現在或曾經患過胃腸道疾病而引致出血性疾病如潰瘍性結腸炎(結腸和直腸的炎症),克羅恩 氏病(腸的炎症),胃或腸癌或憩室炎(結腸中的囊
- 袋發炎或感染)。 如果你正在服用其他非類固醇抗炎藥 (NSAIDs), 包括可選擇環氧化酶 2 抑制劑和乙酰水楊酸(阿士 匹囊),這種物質存在於許多用於舒緩疼痛和退燒
- 如果你正在服用抗凝血劑例如華法林, 香豆素或新 的口服抗凝血劑如阿哌沙班,達比加群及利伐沙班
- 等來預別Ⅲ栓基。 如果你以前曾對匹洛西卡 (piroxicam),其他其他 非類固醇炎消炎藥水NSAID)或其他藥物造成嚴重 的過敏反應,尤其是嚴重的皮膚反應(不論嚴重 程度),例如剝落性皮炎(皮膚強烈變紅,皮膚 鱗屑或層剝落),起水皰反應(史蒂文斯-約翰隆) 縣肩蚁膚剥洛力,起水飑反應(夾帶文則·科賴遊綜合症,以紅色水皰,皮膚糜爛或出血爲特徵)或中毒性表皮壞死症(皮膚淺表層起水皰和脫皮的疾病),或者你曾經歷過其他過敏反應,例如哮喘發作,嚴重的鼻塞或其他過敏反應,例如皮膚痕癢,皮疹,面部,嘴唇或舌頭腫脹,導致呼
- 吸困難或胸部喘鳴 如果您出現皮疹或皮膚症狀,請立即停止服用匹洛西卡,尋求緊急醫療建議,並告知你的醫生你
- 位四下,受办系心質が失年成正在服用這種藥物。 如果你有急性肝臟或腎臟疾病。 如果你有嚴重的心臟衰竭。 如果你有面液凝結障礙。

- 如果你在懷孕期的最後三個月。

如果你屬於以上任何一種情況,切勿服用匹洛西卡 (piroxicam)。並立刻通知你的醫生。

### 警告和預防措施

服用莎華-「炎痛消」之前,請先諮詢你的醫生或藥 劑師。

胃腸道風險

與其他非類固醇消炎藥一樣,莎華-「炎痛消」可能 會對胃和腸引起嚴重的反應,例如疼痛,出血,潰 瘍和穿孔。每天服用超過。20 毫克的劑量會增加胃 湯和安果物果物。 瘍和穿孔。 每天 道副作用的風險。 盡可能使用最低的有效劑量及短 暫使用以減少不良影響

如果你有胃痛或胃或腸出血的跡象,例如糞便黑色或帶血或吐血,應停止服用匹洛西卡治療,並與諮

如果在治療期間出現任何新的腹部症狀或病徵或胃 腸道倂發症,請暫停用藥並立即諮詢醫生。

#### 皮膚風險

有報導稱使用匹洛西卡時皮疹可能會危及生命(史蒂文斯 - 約翰遜綜合症和中毒性表皮壞死症)。 這些皮疹最初表現爲紅色斑點或圓形斑點,通常在中

其他可能出現的症狀包括口腔,喉嚨,鼻,生殖器 潰瘍和結膜炎(雙眼紅腫)。

可能危及生命的皮疹通常伴有類似流感症狀。 皮疹

可能會進展形成大面積的水皰或皮膚剝落。

出現嚴重皮膚反應的最高風險是在治療的最初幾星

如果你在服用匹洛西卡 (piroxicam) 的情況下引致史蒂文斯-約翰遜綜合症或中毒性表皮壞死症,你在任 何時候都不應該再服用這類藥物。

如果你出現皮疹或任何這些皮膚症狀,應停止服用 匹洛西卡 (piroxicam),請立即去看醫生,告訴他你

# 心血管和腦血管風險

心血官和協血官風險 像莎華-「炎痛消」這類的藥物可能會增加心臟病發作(心肌梗塞)或中風的風險。尤其當使用高劑量和 長期治療時,這種風險更容易引發。所以不要超過 建議劑量或治療時間。 如果你有心臟問題,有中風病史或認爲你可能有這 些疾病的風險(例如:你有高血壓,糖尿病,高膽固 醇或吸煙者),使用此藥治療前請先諮詢你的醫生或

此外,這類型的藥物可能導致體液滯留,特別是在 心臟衰竭和或高血壓患者中。

如果你已經超過 70 歲,你的醫生可能會減少治療的時間,並在服用匹洛西卡 (piroxicam) 時更頻密地 進行檢查。

如果你正在服用其他藥物如皮質類固醇或某些抑鬱症藥物,稱爲選擇性. 羥色胺再攝取抑製劑(SSRIs)或乙酰水楊酸以預防血栓形成,你的醫生可能會開 一種保護你的胃或腸的藥物與莎華

如果你已超過80歲,不要服用此藥。

如果你現在或曾經有過任何醫療問題或任何類型的 過敏,或者如果你不確定是否可以服用匹洛西卡 (piroxicam),請在服用此藥前先諮詢你的醫生。

確保你的醫生知道你正在服用的所有藥物,包括那 些無須處方的藥物。 你應謹慎服用莎華-「炎痛消」,並在以下情況下嚴

- 格遵守醫生的指示: - 如果你有中度或輕度腎臟或肝臟疾病。

- 如果你有中度或輕度腎臟或肝臟疾病。 如果你嚴重脫水。 如果你有感染,因爲它可能掩蓋發燒的情況,並錯誤地讓你以爲已經好轉或感染不嚴重。 如果你在使用匹洛西卡 (piroxicam) 治療期間出現眼睛問題,你應該看眼科醫生。 如果你有哮喘。 如果你正在服用抗凝劑。

# 使用其他藥物

請告訴你的醫生或藥劑師,如你正使用、最近使用或打算使用其他藥物。

某些藥物可以相互作用。你的醫生可能會限制你使用匹洛西卡(piroxicam)及/或其他藥物,或者你可能需要改用其他藥物。如果你正在服用以下任何藥 物,告訴你的醫生尤其重要

- 阿士匹靈或其他非類固醇抗炎藥來緩解疼痛

- 防止血小板積聚的藥物,如乙酰水楊酸。
- 鋰(用於躁鬱症的藥物)。 氨甲喋呤(用於類風濕性關節炎和治療某些癌症的

- 氨中噪呤(用於類風濕性關節炎和治療杲些暑症的藥物)。 噻氯匹定(抗血小板藥)。 噻氯酮類(抗感染藥物)。 某些利尿劑(用於治療高血壓中液體滯留的藥物)。 磺脲類(口服降血糖藥)。 環孢素或他克莫司(用於移植患者的藥物)。 抗高血壓藥(用於治療高血壓的藥物)。 流栓溶解劑(用於治療中風或心臟病的藥物)。 池高辛同時使用地高辛和匹洛西卡 (piroxicam)的 治療不影響這兩種藥物之間的血漿水平。

在任何這些情況下,立即通知你的醫生。