在隨後的月經週期增加。 當出現最初症狀時應開始治療。 根據症狀的強烈程度,治療應持續幾天。

服用藥物方法

應當用一杯水或其他液體將整片藥片吞服,不要弄碎或咀嚼藥片。 最好在飯前或空腹服用莎華「達痛靈」(請參閱"莎華「達痛靈」和食物,飲料和酒精"一節)。

#### 如果你服用過量莎華「達痛靈」

如果過量或意外攝入,請立即告訴您的醫生或藥劑師。

#### 如果你忘記服用莎華「達痛靈」

不要服用雙倍劑量來彌補被遺忘的劑量。

#### 4. 可能的副作用

像所有藥物一樣,此藥物可能會引起的副作用,並非所有 人都會有這副作用。

某些副作用可能很嚴重。

如果你發現有以下情況,請停止使用此藥物並立即諮詢醫

在開始使用雙氯芬酸 治療後不久開始出現輕度的腹部絞痛和腹部壓痛,隨後出現直腸出血或帶血性腹瀉, 通常在腹痛發作後24小時內出現(頻率未知,無法從可用數據中估算)。

胸痛. 這可能是潛在的嚴重過敏反應的一種徵兆,稱爲 Kounis 症候群。

使用雙氯芬酸已報告的其他副作用如下:

#### 常見的副作用(最多可能影響10人中的1位):

- 頭昏眼花

耳朵和迷宮疾病

- 眩暈

胃腸道疾病

平原/

- 腹瀉 - 胃灼熱

 腹痛 - 腸胃脹氣

食慾不振

- 肝功能血液檢查結果改變(血清轉氨酶升高)

皮膚和皮下組織疾病

### 不常見的副作用(最多可能影響100人中的1位):

心臟疾病(長期治療時應高劑量服用)

- 心悸 - 尖然的劇烈胸痛(心肌梗塞或心臟病發作的症狀) - 呼吸急促,躺下時呼吸困難,腳或腿腫脹(心臟衰竭的

#### 如果出現這些症狀, 請立即諮詢醫生

#### 罕見的副作用(最多可能影響1000人中的1位):

免疫系統疾病
- 面部、眼睛或舌頭腫脹,吞嚥困難,喘息,蕁麻疹和全身瘙癢,皮疹,發燒,腹部絞痛,胸部不適或氣密,呼吸急促,頭暈,神志不清(嚴重過敏反應)

### 如果出現這些症狀, 請立即諮詢醫生

神經系統疾病

### 如果出現這些症狀, 請立即通知醫生

呼吸,胸和縱隔疾病

- 哮喘

胃腸道疾病

- 月/m - 反流(胃食道逆流)

- 胃潰瘍或小腸潰瘍有或無出血或穿孔(嘔吐血液和糞便

#### 如果出現這些症狀, 請立即諮詢醫生

肝膽疾病

- 肝功能受損 - 肝炎泛黄或不泛黄。

## 如果出現這些症狀, 請立即諮詢醫生

皮膚和皮下組織疾病

- 蕁麻疹

一般性疾病和給藥部位情況 - 體液滯留並出現腫脹(水腫)

### 非常罕見的副作用(最多可能影響10,000人中的1位):

血液和淋巴系統疾病 - 缺乏血細胞的會導致疲倦,頭痛,運動時呼吸急促,頭量,面色蒼白(貧血),發燒,發冷,喉嚨痛或口腔潰瘍(白細胞減少症)頻繁感染,出血或比平常更瘀青(

#### 如果出現這些症狀, 請立即諮詢醫生

免疫系統疾病 面部腫脹

精神病

- 迷惘 - 沮喪 - 失眠

盾躁

- 精神病反應

神經系統疾病

- 刺痛感

癲癇發作

- 腦膜炎(大腦周圍薄膜發炎)病徵如發燒,噁心,嘔 吐,頭痛,頸僵硬或對強光極爲敏感

#### 如果出現這些症狀, 請立即諮詢醫生

- 視野模糊 - 雙重視覺

耳朵和迷宫疾病 - 耳鳴

血管疾病 高血壓(高血壓)

- 血管炎(血管壁發炎)

呼吸,胸椎和縱隔疾病 - 呼吸急促,喘鳴(肺炎)

#### 如果出現這些症狀, 請立即諮詢醫生

隆氏症和潰瘍性結腸炎加重

便秘

医胶 舌頭腫脹(舌炎) 口腔粘膜發炎(口腔潰瘍) 吞嚥問題(食道疾病) 上腹部劇烈疼痛,噁心,嘔吐和食慾不振(胰腺炎跡

#### 如果出現這些症狀, 請立即諮詢醫生

皮膚和皮下組織疾病 - 嚴重的皮膚反應,例如皮疹,發紅,舌頭, 嘴唇或眼睛 出現水泡,皮膚脫皮,並有疲勞,噁心,食慾不振,發 燒,發冷,頭痛,咳嗽或身體疼痛(史蒂文斯-強森綜合 症或毒性表皮溶解症)

#### 如果出現這些症狀, 請立即諮詢醫生

- 全身性皮疹(濕疹) - 發紅(紅斑和多形性紅斑)

皮膚脫皮(脫落性皮炎)

- 脫髮 - 陽光過敏(光敏感反應)

- 痞癢

腎臟和泌尿系統疾病 - 臀功能受損,導致腳或腿腫脹和尿量突然減少(急性腎 衰竭,間質性腎炎,腎乳頭壞死) - 尿液中帶有血液(血尿)

- 尿液有泡沫(腎病綜合症)

#### 如果出現這些症狀, 請立即諮詢醫生

個別的案例

·肝功能異常,導致皮膚和眼睛發黃,發燒,腸道上部疼 痛和瘀青(肝衰竭,暴發性肝炎,肝壞死)

#### 如果出現這些症狀, 請立即諮詢醫生

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。

### 5. 如何貯存莎華「達痛靈」

請將本藥存放於兒童視線範圍以外及不能觸及的地方。

請勿儲存於攝氏25度以上。 在藥盒上"EXP"標明的日期之後,請勿使用此藥。 到期日

是指該月的最後一天。 請勿通過廢水或家居垃圾丟棄任何藥物。 諮詢藥劑師如何 丟棄不再使用的藥物。 這些措施將有助於保護環境。

### 6. 包裝和其他資訊

莎華「達痛靈」包含甚麼

主要成份: 每粒藥片含50毫克雙氯芬酸鈉

案片核心其他成份: lactose monohydrate, microcrystalline cellulose (E-460), maize starch, croscarmellose sodium, colloidal anhydrous silica, sodium lauryl sulphate, povidone (E-1201), talc (E-553b), magnesium stearate (E-470B).

藥片塗層: hydroxypropyl methylcellulose (E-464), methacrylic acid copolymer and ethyl acrylate (1: 1) 30% dispersion, triethyl citrate (E-1505), talc (E-553b), titanium dioxide (E-171) ), yellow iron oxide (E-172), brown iron oxide (E-172).

#### 莎華「達痛靈」的外觀和包裝內容

淺棕色雙凸圓柱形片劑,藥片上並標記有代碼" D50C"。 它們以 PVC-PVDC/鋁泡罩形式供應。 每包包含 40粒腸溶

#### 營銷授權持有人和製造商:

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

說明書最後修訂日期: 2023年3月

#### 代理商

香港威非路道18號萬國寶通中心30樓3001室

傳真: 2470 3448 HK Reg. No. HK- 51134



Package leaflet: information for the user

# diclofenac cinfa 50 mg gastro-resistant tablets

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 signs of illness

- 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 diclofenac cinfa is and what it is used for
2. What you need to know before taking diclofenac cinfa

3. How to take diclofenac cinfa4. Possible side effects5. How to store diclofenac cinfa

6. Contents of the pack and other information

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

Diclofenac sodium, the active substance in diclofenac cinfa, belongs to the group of medicines called non-steroidal anti-inflammatory drugs, which are used to treat pain and inflammations. inflammation.

Diclofenac cinfa is used to treat the following conditions:
- Chronic inflammatory rheumatic diseases (rheumatoid arthritis, ankylosing spondylitis, osteoarthritis),

Extra-articular rheumatism. Acute attacks of gout,

Period pains,Post-traumatic inflammation.

2. What you need to know before taking diclofenac cinfa It is important that you use the lowest dose that relieves/controls the pain and you must not take this medicine for longer than required to control your symptoms.

the pain and you must not take this medicine for longer than required to control your symptoms.

Do not take diclofenac cinfa:

- if you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6).

- if you are allergic or have had allergic reactions to acetylsalicylic acid (aspirin) or other similar analgesics (medicines used to treat pain). Reactions may include asthma (difficulty breathing), chest pain, urticaria (allergic skin reaction with itching), acute rhinitis (inflammation of the nasal mucosa) or swelling of the face, lips, tongue, throat and/or extremities (signs of angioedema). If you believe you may be allergic, consult your doctor.

- if you have previously experienced stomach or duodenal bleeding or have experienced, on two or more occasions, perforation of the digestive tract while taking a non-steroidal anti-inflammatory drug.

- if you currently suffer or have suffered on more than one occasion from stomach or duodenal ulcer or bleeding.

- if you currently suffer or have suffered on more than one occasion from stomach or duodenal ulcer or bleeding.

- if you suffer from active ulcerative colitis or Crohn's disease (diseases that cause diarrhoea with or without blood and abdominal pain).

- if you suffer from severe kidney disease.

- if you have severe liver disease.

- if you have established heart disease and/or cerebrovascular disease, for example, if you have had a heart attack, stroke, mini-stroke (TIA) or blockages in the blood vessels of the heart or brain, or a coronary bypass or operation to eliminate an obstruction.

obstruction.

if you have or have had blood circulation problems (peripheral arterial disease).

if you are in the last trimester of pregnancy.

if you suffer from a blood clotting disorder.

if you think you may be allergic to diclofenac sodium, acetylsalicylic acid, ibuprofen or any other NSAID, or any of the other components of diclofenac. (Listed at the end of the package insert.) Signs of a hypersensitivity reaction are swelling of the face and mouth (angioedema), trouble breathing, chest pain, runny nose, rash or any other allergic reaction.

Before taking diclofenac, make sure your doctor knows:

 if you smoke.
 if you have diabetes. if you have angina, blood clots, high blood pressure, high cholesterol or high triglycerides.

Adverse effects can be minimised by using the lowest effective dose for the shortest possible time.

Warnings and precautions Talk to your doctor or pharmacist before taking diclofenac cinfa.
 If you have had or develop an ulcer, bleeding or perforation in the stomach or duodenum, which can manifest as severe, persistent abdominal pain and/or black stools, or even without

persistent abdominal pain and/or black stools, or even without previous warning symptoms.

This risk is higher when high doses and long-term treatments are used in patients with a history of peptic ulcer and in elderly patients. In these cases, your doctor will consider using a stomach protecting medicine.

If you suffer from any of the following conditions: asthma, mild heart disease, liver or kidney disease, high blood pressure (hypertension), bleeding disorders or other blood disorders including hepatic porphyria.

If you are taking other anti-inflammatory medicines, corticosteroids, anticoagulants or antidepressants, as they increase the risk of ulcers and/or gastrointestinal bleeding (see section "Other medicines and diclofenac cinfa").

If you are taking blood pressure medicines or ciclosporin, as they increase the risk of kidney damage (see section "Other medicines and diclofenac cinfa").

Talk to your doctor:
- If you concomitantly take medicines that affect blood clotting If you concomitantly take medicines that affect blood clotting or increase the risk of ulcers, such as oral anticoagulants or platelet aggregation inhibitors, such as acetylsalicylic acid. You must also report the use of other medicines that could increase the risk of bleeding, such as corticosteroids and selective serotonin reuptake inhibitor antidepressants.

If you suffer from Crohn's disease or ulcerative colitis, as medicines like diclofenac can exacerbate these conditions.

If you have high blood pressure, high cholesterol or triglyceride levels, diabetes or are a smoker (cardiovascular risk factors), your doctor should periodically re-evaluate whether you should continue your treatment with diclofenac, especially if you have been taking it for more than 4 weeks.

If you have liver failure, kidney failure or blood disorders, you will need frequent blood tests during your treatment. This will make it possible to control your liver (transaminase level), kidney (creatinine level) or blood (lymphocyte, erythrocyte and platelet levels) function. Your doctor may therefore decide to stop or change your dose of diclofenac.

- Tell your doctor if you have recently undergone or are due to undergo surgery on your stomach or intestine before taking diclofenac, as diclofenac can sometimes worsen wound healing after surgery.

Patients with cardiovascular problems

Patients with cardiovascular problems
Medicines such as diclofenac can be associated with an increased risk of heart attack ("myocardial infarction") or stroke, especially when used in high doses and in prolonged treatments. Do not exceed the recommended dose or duration of treatment, If you have heart problems, a history of stroke or think you may be at risk (for example, if you have high blood pressure, diabetes, elevated cholesterol or triglycerides, or are a smoker) and your doctor decides to prescribe diclofenac, you should not take more than 100 mg a day if the treatment lasts more than 4 weeks than 100 mg a day if the treatment lasts more than 4 weeks. Furthermore, this type of medicine can cause fluid retention, particularly in patients with heart disease and/or high blood pressure (hypertension).

In general, it is very important to take the lowest effective dose of In general, it is very important to take the lowest effective dose of diclofenac for the shortest possible time that relieves pain and/or inflammation in order to reduce the risk of adverse cardiovascular effects. If you notice chest pain, shortness of breath, weakness or difficulty speaking while you are taking diclofenac, contact your doctor immediately.

# **Children and adolescents**Not recommended for use in children and adolescents under 14 years of age.

Use in elderly patients Ose in enterly patients. Elderly patients may be more sensitive to the effects of diclofenac than other adults, especially if they are frail or have a low body weight. For this reason, it is especially important that elderly patients inform the doctor immediately of any adverse effects.

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

Some medicines can interact with diclofenac; in these cases, it may be necessary to change the dose or stop treatment with some of the medicines.

It is important that you inform your doctor if you are taking, or have recently taken, any of the following medicines:

- medicines that contain lithium or serotonin reuptake inhibitors (to treat some types of depression)

medicines that contain methotrexate (to treat rheumatoid arthritis and cancer),
medicines that contain ciclosporin, tacrolimus (for after transplants), medicines that contain trimethoprim (to prevent and treat

urinary tract diseases), medicines to treat heart problems (digoxin, calcium channel blockers such as verapamil or isradipine), medicines used to treat diabetes, except insulin.

epileptic seizures).

 - medicines to control blood pressure (diuretics, beta blockers and ACE inhibitors),
 - medicines to prevent blood clots,
 - medicines that contain quinolone or ceftriaxone (to treat infections).

other medicines from the same group as diclofenac (non-steroidal anti-inflammatory drugs) such as acetylsalicylic acid or ibuprofen, corticosteroids (medications that reduce inflammation and the

action of the immune system), medicines that contain voriconazole (a medicine used in the treatment of fungal infections), medicines that contain phenytoin (a medicine used to treat

medicines that contain misoprostol (to treat stomach ulcers), medicines that contain cholestyramine and colestipol (to lower blood cholesterol). medicines that contain pentazocine (to relieve pain)

diclofenac cinfa with food, drink and alcohol
This medication should be taken preferably before meals or on an
empty stomach as it delays the onset of the effect.

an antibiotic medicine used to treat bacterial infections

The intake of alcoholic beverages together with diclofenac may

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

advice before taking this medicine.

Pregnancy
Do not take diclofenac if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. Since the administration of medicines like diclofenac has been associated with an increased risk of suffering congenital anomalies/miscarriages, its administration is not recommended during the first and second trimester of pregnancy, unless it is considered to be completely necessary and as indicated by your doctor. In these cases the dose and duration will be limited to the minimum possible. If taken for more than a few days from 20 weeks of pregnancy onward, diclofenac can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. For women of child-bearing potential, it must be considered that medicines like diclofenac have been associated with reduced fertility.



# Breast-feeding Ask your doctor or pharmacist for advice before using any medicine. Small amounts of diclofenac may be found in breast milk, so you should not take diclofenac if you are breast-feeding.

Driving and using machines
Diclofenac has no or negligible influence on the ability to drive and use machines, but patients who experience visual disturbances, dizziness, vertigo, drowsiness or other disorders of the central nervous system while being treated with diclofenac should avoid driving vehicles or operating machinery.

diclofenac cinfa contains lactose.

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

 $\begin{array}{l} \mbox{diclofenac cinfa contains sodium.} \\ \mbox{This medicine contains less than } 1 \mbox{ mmol of sodium (23 mg) per tablet; it is essentially "sodium-free".} \end{array}$ 

#### 3. How to take diclofenac 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. Remember to take your medicine.

Use in adults and children over 14 years of age
The recommended dose for milder cases is 100 mg (one tablet twice
daily). Do not exceed the dose of 150 mg (3 tablets) per day. The total
daily dose should be divided into 2 or 3 separate doses.

For period pains, the daily dose, which must be adjusted individually, is 50-200 mg (1 to 4 tablets). An initial dose of 50-100 mg (1 to 2 tablets) will be administered and it will be increased in the following menstrual cycles if necessary. Treatment should be initiated when the first symptoms appear. Depending on their intensity, the treatment should be taken for a few days.

Method of administration
The tablets should be swallowed whole with a glass of water or other liquid, without breaking or chewing them. Take diclofenac preferably before meals or on an empty stomach (see section "diclofenac cinfa with food, drink and alcohol").

If you take more diclofenac cinfa than you should In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately.

If you forget to take diclofenac cinfa
Do not take a double dose to make up for a forgotten dose.

#### 4. Possible side effects

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

Some side effects may be serious.

Stop using this medicine and consult your doctor immediately if you

Mild abdominal cramping and abdominal tenderness that begins soon after starting treatment with diclofenac followed by rectal bleeding or bloody diarrhoea, normally seen within 24 hours after the onset of abdominal pain (frequency unknown, cannot be estimated from the available data).

Chest pain, which may be a sign of a potentially severe allergic reaction called Kounis syndrome.

Other side effects that have been reported with the use of diclofenac are the following

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

Nervous system disorders

headache
light-headedness

Ear and labyrinth disorders

Gastrointestinal disorders

- nausea
- vomiting
- diarrhoea
- heartburnabdominal painflatulence
- loss of appetite
- Henatohiliary disorders

repationary in liver function blood test results (increased serum transaminases) Skin and subcutaneous tissue disorders

#### Uncommon side effects (may affect up to one in 100 people):

Cardiac disorders (at high doses during prolonged treatments)

- palpitations
 - severe sudden chest pain (symptoms of myocardial infarction or

heart attack) shortness of breath, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)

#### If these symptoms occur, consult your doctor immediately Rare side effects (may affect up to one in 1,000 people):

Immune system disorders

mmunie system disorders swelling of the face, eyes or tongue, difficulty swallowing, wheezing, hives and generalised itching, skin rash, fever, abdominal cramps, chest discomfort or tightness, shortness of breath, dizziness, unconsciousness (severe allergic reaction)

#### If these symptoms occur, consult your doctor immediately

Nervous system disorders

#### If these symptoms occur, consult your doctor immediately

Respiratory, thoracic and mediastinal disorders

Gastrointestinal disorders

- reflux
   bloody diarrhoea
- gastric or intestinal ulcer with or without bleeding or perforation (vomiting of blood and appearance of blood in stool).

### If these symptoms occur, consult your doctor immediately

Hepatobiliary disorders
- impaired liver function

- hepatitis with or without vellowing.
- If these symptoms occur, consult your doctor immediately

Skin and subcutaneous tissue disorders

General disorders and administration site conditions fluid retention with swelling (oedema

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

Blood and lymphatic system disorders - signs of a lack of blood cells resulting in tiredness, headache, shortness of breath when exercising, dizziness, paleness (anaemia), frequent infections with fever, chills, sore throat or mouth ulcers (leukopenia), bleeding or more bruising than usual (thrombocytopenia)

#### If these symptoms occur, consult your doctor immediately

Immune system disorders

swelling of the face

- Psychiatric disorders

- depression insomnia
- nightmares irritability psychotic reactions
- Nervous system disorders
- tingling sensation memory disorders
- anxiety
- tremors
- meningitis (inflammation of the membranes that surround the brain) with symptoms such as fever, nausea, vomiting, headache, stiff neck or extreme sensitivity to bright light.

#### If these symptoms occur, consult your doctor imme

cerebral infarction

Eye disorders
- blurred vision
- double vision

Ear and labvrinth disorders

- ringing in the ears

- Vascular disorders
   hypertension (high blood pressure)
   vasculitis (vessel wall inflammation)
- Respiratory, thoracic and mediastinal disorders

shortness of breath, wheezing (pneumonitis)

### If these symptoms occur, consult your doctor immediately

- Gastrointestinal disorders
   exacerbation of Crohn's disease and ulcerative colitis

- constipation
   swelling of the tongue (glossitis)
   inflammation of the mucosa of the mouth (stomatitis)
   problems swallowing (oesophagus disorders)
   severe pain in the upper abdomen, nausea, vomiting and loss of appetite (signs of pancreatitis).

### If these symptoms occur, consult your doctor immediately

Skin and subcutaneous tissue disorders
- severe skin reactions with rash, redness, blisters on the lips, mouth or eyes, peeling skin, accompanied by fatigue, nausea, loss of appetite, fever, chills, headache, cough or body aches (Stevens-Johnson syndrome or toxic epidermal necrolysis).

### If these symptoms occur, consult your doctor immediately

- redness (erythema and erythema multiforme)
   redness (erythema and erythema multiforme)
   peeling skin (exfoliative dermatitis)
   hair loss
   sun allergy (photosensitivity reaction)
- bruising

- Renal and urinary disorders
   impaired kidney function, which causes swelling in feet or legs and sudden decrease in urine quantity (acute renal failure, interstitial nephritis, renal papillary necrosis)
- blood in urine (haematuria) - foamy urine (nephrotic syndrome)

# If these symptoms occur, consult your doctor immediately

Isolated cases Hepatobiliary disorders

repaircularly users abnormalities in the functioning of the liver that cause yellowing of the skin and eyes, fever, pain in the upper part of the gut, and bruising (liver failure, fulminant hepatitis, hepatic necrosis)

#### If these symptoms occur, consult your doctor immediately

Reporting of side effects

reporting of size effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### 5. How to store diclofenac cinfa

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

Do not store at temperatures above 25°C.

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 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 diclofenac cinfa contains

what ductorenac cintra contains

The active substance is diclofenac sodium. Each gastro-resistant tablet contains 50 mg of diclofenac sodium.

The other ingredients (excipients) are:

Core: lactose monohydrate, microcrystalline cellulose (E-460),

maize starch, croscarmellose sodium, colloidal anhydrous silica, sodium lauryl sulphate, povidone (E-1201), talc (E-553b), magnesium stearate (E-470B).

Coating: hydroxypropyl methylcellulose (E-464), methacrylic acid copolymer and ethyl acrylate (1: 1) 30% dispersion, triethyl citrate (E-1505), talc (E-553b), titanium dioxide (E-171), yellow iron oxide (E-172), brown iron oxide (E-172).

What diclofenac cinfa looks like and contents of the pack Light brown biconvex cylindrical tablets, coated and marked with the code "D50C".

They are supplied in PVC-PVDC/Aluminium blisters. Each pack contains 40 gastro-resistant tablets.

# Marketing authorisation holder and manufacture

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

This leaflet was last revised in March 2023.



# 莎華「達痛靈」 50 毫克

#### 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查詢
- 班等只處方給你,請勿給其也久未用即是副。 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,請諮詢你的醫生或藥劑師,此包括任何未有在此說明書列出的任何可能的副作用。請參閱第4節。

#### 此說明書包含甚麽資料?

- 1. 莎華「達痛靈」是甚麼及用於甚麼情况 2. 使用莎華「達痛靈」前你需要留意甚麼 3. 如何使用莎華「達痛靈」 4. 可能的副作用

- 5. 如何貯存莎華「達痛靈」 6. 包裝及其他資料

### 1. 莎華 - 「達痛靈」是甚麼及用於甚麼情況

雙氯芬酸鈉是莎華「達痛靈」的活性物質,屬於被稱爲非 類固醇抗炎藥的藥物類別,用於治療疼痛和炎症

- 莎華「達痛靈」用於治療以下疾病引起的疼痛: 慢性風濕病引起的炎症,
- 急性痛風發作,
- 創傷後炎症

### 2. 服用莎華「達痛靈」前, 您需要留意甚麼

你應使用能減輕/控制疼痛的最低劑量是最爲重要的,並且 你不應服用此藥的時間長於能控制症狀所需的時間

在以下情況不應服用莎華「達痛靈」

- 如果你對此藥物的活性物質或其他任何成分過敏(在第6節中列出)。 - 如果你對乙醯水楊酸(阿司匹靈)或其他類似的鎮痛藥 - 如果你對乙醯水楊酸(阿司匹靈)或其他類似的鎮痛藥( 用於治療疼痛的藥物)過敏或曾經有過敏反應。過敏反應 包括哮喘(呼吸困難),胸痛,蕁麻疹(皮膚琼癢的過敏 反應),急性鼻炎(鼻粘膜發炎)或面部、嘴唇、舌頭、 喉嚨和或四肢腫脹(血管性水腫的跡象)。如果你認為 自己可能過敏,請諮詢醫生。 - 如果你曾經有過胃部或十二指腸出血,或者在服用非類固 醇消抗炎藥時兩次或多次發生消化道穿孔。 如果你目前或曾經出現胃部或十二指腸溃傷場出血。 - 如果你思有活躍潰瘍程結腸炎或克隆氏症(導致出血或非 出血的腹瀉疾病和腹痛)。 - 如果你患有嚴重的腎臟疾病。 - 如果你患有嚴重的腎臟疾病。 - 如果你患有嚴重的肝臟疾病。 - 如果你是有嚴重的肝臟疾病。 - 如果你是有嚴重的肝臟疾病。

- 如果你患有嚴重的肝臟疾病。 如果你已確定患有心臟病和/或腦血管疾病,例如曾經患有心臟病,中風,小中風(TIA)或心臟或腦血管阻塞或冠狀動脈搭橋備或手術消除障礙物。 如果你有或曾經有血液循環問題(周邊動脈阻塞性疾病)。 如果你正處於妊娠的最後三個月。 如果你患有凝血障礙。 如果你認爲自己可能對雙氯芬酸鈉,乙醯水楊酸,布洛芬或任何其他非類固醇消炎藥過敏,或者對雙氯芬酸 的任何成分過敏。(在本說明書最後部份列出)。過敏反應的病徵是臉部和嘴部腫脹(血管性水腫),呼吸困難,胸痛、流鼻涕,皮疹或任何其他過敏反應。

# 在服用 雙氯芬酸之前,請確保你的醫生知道:

- 如果你抽煙
- 如果你患有糖尿病 知果你思有植物病。 如果你患有心絞痛,血液凝塊,高血壓,高膽固醇或高三 酸甘油酯。 可以通過在最短的時間服用最低有效劑量亦 能在最大程度上減少不良影響。

警告和注意事項: 服用莎華「達痛靈」之前,請先向你的醫生或藥劑師諮

- 可。 如果你患有胃部或十二指腸有潰瘍,出血或穿孔,並有可 能顯得嚴重,持續性腹痛和/或糞便黑色,甚至沒有任何的
- 便用胃部保護樂。 - 如果你患有以下任何一種疾病:哮喘,輕度心臟病,肝臟 或腎臟疾病,高血壓(高血壓),出血性疾病或其他血液 疾病,包括肝卟啉症。 - 如果你正在服用其他消炎藥,皮質類固醇,抗緩劑或抗却
- 如宋你正任版用共配相交樂,及真賴自辟,扎歲南級加邦 鬱藥,因爲它們會增加潰瘍和/或胃腸道出血的風險(請 參閱"服用其他藥物"一節)。 如果你正在服用降壓藥或環孢素,因爲它們會增加腎臟損 害的風險(請參閱"服用其他藥物"一節)。

# 請告知你的醫生:

- 如果你同時服用影響血液凝固或增加潰瘍風險的藥物, 如二服抗凝藥或血小板抑制 劑,例如乙醯水杨酸。你必須昭眠抗凝藥或血小板抑制 劑,例如乙醯水杨酸。你必須報告使用其他可能增加出血風險的藥物,例如皮質類固醇和選擇性5.經色胺再攝取抑製劑抗抑鬱藥。 如果你有克隆氏症或潰瘍性結腸炎,像雙氯芬酸 這樣的
- 知来你有兒童八班或貨物日和協交,像受象分散 這樣的藥物可能會加重病情。
   如果你患有高血壓,高膽固醇或三酸甘油酯水平,糖尿病或吸煙(心血管危險因素),你的醫生應定期重新評估是否應繼續使用莎華「達痛靈」進行治療,尤其是你一直服用該藥時超過4週。
- 用該樂時超過4週。 如果你患有肝臟衰竭,腎臟衰竭或血液疾病,在治療期間 需要經常進行血液檢查。這樣就可以控制肝臟(轉氨酶水 平),腎臟(肌酸酐水平)或血液(淋巴細胞,紅細胞和 血小板水平)的功能。因此,你的醫生可能決定停止或更
- 立雙氯芬酸的劑量。 在服用雙氯芬酸之前,告訴您的醫生您最近接受過或即將接受胃或腸道手術,因爲雙氯芬酸有時會惡化手術後的傷

# 有心血管問題的患者

有心血管問題的患者 例如雙氯芬酸之類的藥物可能會增加心臟病發作("心肌梗塞")或中風的風險,特別是在高劑量和長期治療中使用時。請勿超過建議的劑量或治療持續時間。如果你有心臟問題,有中風病史或認為你可能處於危險之中(例如,如果你患有高血壓,糖尿病,高膽固醇或高三酸甘油酯或吸煙者),而你的醫生決定處方雙氯芬酸,如果持續治療超過4週,你不應每天服用多於100毫克。

此外,此類藥物會導致體液滯留,特別是在患有心臟病和/ 或高血壓(高血壓)的患者中。

一般而言,盡可能在短時間內服用最低有效劑量的雙氯芬酸,以減輕疼痛和J或炎症,從而降低心血管不良反應的風險。 如果你在服用雙氯芬酸發現胸痛,呼吸急促,虛弱或說話困難,請立即聯絡你的醫生。

#### 兒童和青少年

不建議兒童和14歲以下的青少年服用。

#### 用於老年患者

70% 2 不必可能比其他成年人對雙氯芬酸的作用更爲敏感, 老年患者可能比其他成年人對雙氯芬酸的作用更爲敏感, 尤其是當他們體弱或體重較輕時。 因此,老年患者有任何 不良反應,應立即告知醫生,這是十分重要的。

### 其他藥物和莎華「達痛靈」

各語來的問生或藥劑師你是否正在服用,最近服用過或可能服用了其他藥物。 有些藥物可以與雙氯芬酸 有相互作用。在這些情況下,可能有必要更改劑量或停止某些藥物的治療。

- 重要的是,如果你正在服用或最近服用以下任何一種藥 勿,請告知你的醫生: 含有鋰或5-羥色胺再攝取抑制劑的藥物(用於治療某類型的抑鬱症),
- 含有甲氨蝶呤的藥物(用於治療類風濕性關節炎和癌症),
- 百月丁氨酸中的类似(用於石原來與風盛日廟即次和福亞) 含有環境素,他克莫百的藥物(用於移植後), 含有甲氧苄啶的藥物(預防和治療尿道疾病), 治療心臟疾病的藥物(地高辛,鈣離子通道阻斷劑,如維
- 拉帕米或伊拉地平), 除胰島素外,用於治療糖尿病的藥物。 控制血壓的藥物(利尿劑,β受體阻斷劑和血管張力素轉 化酶抑制劑), 預防血液凝塊的藥物
- 含有喹諾酮或頭孢曲松(治療感染)的藥物, 與雙氯芬酸(非類固醇消炎藥)同類別組的其他藥物,例

- 與雙氯分酸(非賴固醇消炎樂)同類別組的其他樂物如乙醯水楊酸或布洛芬。
  皮質類固醇(減少炎症和免疫系統作用的藥物),
  含有状立康唑的藥物(用於治療真菌感染的藥物),
  含有苯妥英鈉(用於治療癲癇發作的藥物)的藥物,
  含有米索前列醇的藥物(用於治療胃潰瘍),
  含有考来烯胺和考来替泊(降低血液膽固醇)的藥物
  含有喷他佐辛(舒緩疼痛)的藥物。
  一種用於治療細菌感染的抗生素藥物(利福平)。

## 莎華「達痛靈」與食物, 飲料和酒精

藥物最好在飯前服用或空腹服用,因爲它會延遲藥物作用 的發作 含酒精的飲料與雙氯芬酸一起服用可能會增加其毒性。

懷孕, 母乳喂養和生育

如果你是孕婦或哺乳期,認爲你可能已經懷孕或打算生孩子,請在服用此藥物之前向你的醫生或藥劑師諮詢。 如果您處於懷孕期最後3個月,請勿服用雙氯芬酸,。因爲它可 如果您處於懷孕期最後3個月,請勿服用雙氯芬酸。因爲它可能會傷害您未出生的孩子或導致分娩的問題。 它可能會導致未出生嬰兒有腎臟和心臟問題。 它可能會影響您和您的嬰兒有出血傾向,並導致分娩比預期稍運或較長時間。 由於服用雙氯芬酸等藥物會增加先天性異常流產的風險,因此不建議在懷孕的第一和第二期服用此藥,除非認爲完全有必要並且是經醫生指示。 在這情況下,劑量和持續時間將被限製到盡可能最少。 如果從懷孕20週開始服用雙氯芳酸多於數天,可能會導致未出生嬰兒有腎臟問題,從而導致嬰兒問圍羊水含量低(羊水過少)或嬰兒心臟血管(動脈導管)變窄。 如果您需要治療的時間多於數天,您的醫生可能會建議進行額外的監測。 對於有生育能力的女性,必須考慮到雙氯芬酸等藥物與生育能力下降有關。

無土部 使用任何藥物之前,請先諮詢你的醫生或藥劑師。 母乳中可能存在少量雙氯芬酸,因此,如果你是母乳喂養,則不應服用雙氯芬酸。 駕駛和使用機器 雙氨芬酸對驚駛和使用機器的能力沒有影響或影響輕微,但患者在服用雙氯芬酸治療時如有視覺障礙、頭暈、眩暈、暫睡或其他中樞神經系統疾病,則應避発駕駛車輛或操

#### 作機器 莎華「達痛靈」含有乳糖

如果你的醫生告訴你對某些糖有不耐受問題,請在服用此 藥物前先諮詢你的醫生。 莎華「達痛靈」含有鈉。 此藥每片含有少於 1 毫摩爾鈉(23 毫克);它基本上是"無納"的。

# 3. 如何服用莎華「達痛靈」

適用於成人和14歲以上的和兒童

務必完全按照醫生或藥劑師的指示服用此藥。 如果不確定,請諮詢你的醫生或藥劑師。 謹記服用藥物。

對於較輕的情況,建議的劑量爲100毫克(每天兩次,每次一粒)。每天的劑量不應超過150毫克(3片)。每日總劑量應分爲2或3次。 對於經痛,必須個別調整 每日劑量爲50-200毫克 (1-4 片)。 初始劑量爲50-100毫克 (1-2片),如有必要,將