

# BREXIN<sup>®</sup> TABLET

Piroxicam (20mg)

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## What Brexin Tablet is used for

Brexin Tablet is an anti-inflammatory and anti-pain drug, used to relieve some symptoms caused by rheumatic disease like rheumatoid arthritis, osteoarthritis (degenerative joint disease). It can also help to relieve inflammation/irritation of the tendon, inflammation of the joint, post-traumatic pain, post-operative pain and menstrual pain.

## How Brexin Tablet works

Piroxicam is a nonsteroidal anti-inflammatory drug (NSAID). This medicine works by reducing substances in the body that cause pain and inflammation.

## Before you use Brexin Tablet

### - When you must not use it

Do not take Brexin Tablet:

- If you are allergic (hypersensitive) to piroxicam or to any of the excipients of Brexin Tablet.
- If you currently or previously had a stomach or intestinal ulcer, bleeding or perforation.
- If you previously had a serious allergic drug reaction to piroxicam, other NSAIDs and other medications, especially serious skin reactions (regardless of severity) such as multiform erythema, exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), vesiculo-bullous reactions: Stevens-Johnson syndrome, a condition with red blistered, eroded, bloody or crusted skin, and toxic epidermal necrolysis, a disease with

blistering and peeling of the top layer of skin.

- If you are or suspect to be pregnant.
- If you are breast-feeding.
- If you are aged less than 18 years.
- If you have a severe liver disease.
- If you have a severe kidney disease.
- If you have severe blood alterations.
- If you have haemorrhagic diathesis (predisposition to frequent bleeding).

If any of these applies to you, you should not be given Brexin Tablet. Tell your doctor immediately.

### - Before you start to use it

Treatment should always be initiated by a physician experienced in the treatment of rheumatic diseases. Tell your doctor:

- If you have a heart disease, heart failure or stroke, hypertension (high blood pressure) or other condition predisposing to oedema (water retention).
- If you are asthmatic.
- If you have problem with your vision.
- If you are diabetic.
- If you have or had any medical problems or any allergies/skin reactions.
- If you had symptoms of asthma, rhinitis, nasal polyposis, angioedema or rash during treatment with acetylsalicylic acid or other NSAIDs.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor may limit your use of piroxicam or other medicines, or you may need to take a different medicine.

It is especially important to mention if you are taking:

- aspirin or other non-steroidal anti-inflammatory drugs for pain relief.
- steroids, which used to treat such as allergies and hormone imbalances.
- anticoagulants to prevent blood clots.
- If you are taking certain drugs for depression called selective

serotonin re-uptake inhibitors (SSRI).

- NSAIDs, including selective inhibitors of COX-2 and acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever). Remember that many NSAIDs can be purchased without prescription.
- Medicines to prevent platelet clumping.
- Diuretics or antihypertensive medicines,
- Lithium or other medicines, for depression.
- Quinolone, used to treat bacterial infections.
- If you use intra-uterine devices

## How to use Brexin Tablet

### - How much to use

Always use Brexin Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

Adults and the elderly:

The maximum daily dose is 20 milligrams of piroxicam as one single daily dose. If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment.

Your doctor may prescribe piroxicam with another medicine to protect your stomach and intestine for potential side effects.

Do not increase the dose.

### - When to use it

Use as directed by your doctor or pharmacist. Your doctor or pharmacist will decide when it is appropriate for you to take Brexin Tablet according to the type of condition you are having.

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## - How long to use it

Follow any recommendations and advices from your doctor or pharmacist. Treatment should be reviewed after 14 days.

## - If you forget to use it

Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. Do not double the dose.

## - If you use too much (overdose)

Symptoms: The most significant overdose symptoms are headache, drowsiness, dizziness and fainting.

In case of accidental intake of an excessive dose of Brexin Tablet inform immediately your doctor or go to the nearest hospital.

## While you are using it

### - Things you must do

Always use Brexin Tablet exactly as your doctor has told you. You must check with your doctor or pharmacist if you are not sure.

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

### - Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not give Brexin Tablet to anyone else without consulting the doctor, even if they have the same symptoms or condition as you.
- Do not drink alcohol during treatment with Brexin Tablet.

### - Things to be careful of

- In case of dizziness or unusual tiredness, pay particular attention when driving or operating machines.
- The dosage forms tablets contain lactose: if you have a diagnosed intolerance to some sugars, contact your doctor before taking Brexin Tablet.
- If you take piroxicam for long term, you should be checked by a doctor to avoid occurrence of unwanted side effects.

## Side effects

Like all medicines, Brexin Tablet can cause side effects, although not everybody gets them. If you developed any of the following side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital.

It is advisable to consult doctor/pharmacist for further information.

## Most common effects:

- Gastric disturbances, nausea, diarrhoea, flatulence, epigastric (upper middle region of abdomen) pain.

## Less common effects:

- Hypersensitivity reaction eg. rash, headache, dizziness, discomfort, drowsiness, dizziness, tinnitus (ringing in the ear), hearing loss, asthenia (lack of energy), change of blood parameters, jaundice (yellow coloured skin or eyes).

## Rare effects:

- Gastric ulcer, with or without bleeding, gastric perforation, swelling of hands and face, increase of photo-sensitivity, vision disturbance, aplastic and haemolytic anaemia (bone marrow failure disorder), inflammation of liver, inflammation of pancreas, kidney disorder, presence of blood in urine, pain or discomfort during urinating, cardio-vascular disturbances eg. high blood pressure, sweating, low level of sugar in blood, high level of sugar in blood, body weight changes, erethism (high degree of sensitivity in any part of body), sleeplessness, bladder disorder, hair loss, impairment of nail growth, mouth dryness, depression, skin disorders, eg. Steven Johnson's syndrome, Lyell's syndrome and multiform erythema, inflammation of mouth, nose bleed, vomiting of blood, black bloody stools and skin peeling.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public->Reporting Medicinal problems/Side Effects/AEFI/ Vaccine Safety).

## Storage and Disposal of Brexin Tablet

### - Storage

Keep Brexin Tablet out of reach and sight of children.

Store below 30°C. Keep container well closed and protect from light. Do not use the product beyond the expiry date indicated on the outer pack and the inner label.

### - Disposal

Medicines should not be disposed in water or domestic waste. Ask your pharmacist about how to dispose not used medicines. This will help protect the environment.

## Product Description

### - What it looks like

Brexin Tablet for oral administration is a hexagonal, pale-yellow homogeneous in colour both inside and on the surface. Median scoring line on one side. Thickness 4.3mm approx.

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**- *Ingredients***

Active Ingredient (s):

Piroxicam-beta-cyclodextrin

Inactive Ingredient (s):

Lactose, cospovidone, sodium starch glycolate, silica, colloidal hydrated, starch, pregelatinised, magnesium stearate.

**-*MAL number***

MAL19992991AZ

**Manufacturer**

Chiesi Farmaceutici SPA

Via Palermo, 26/A 43100 Parma

Italy.

**Product Registration Holder**

Germax Sdn. Bhd.

10, Jalan PJU 3/48,

Sunway Damansara Technology Park,

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23/11/2017

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