

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)

- 1986

This medicine is dispensed with a doctor's prescription only

BREXIN

Tablets

Active ingredient:

Each tablet contains: piroxicam (as beta-cyclodextrin) 20 mg

List of inactive ingredients and allergens in this medicine: See section 6 'Additional information' and section 2 under 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

An anti-inflammatory medicine and pain reliever used to relieve symptoms such as pain, swelling and stiffness in the joints that are due to rheumatic illnesses or to ankylosing spondylitis.

Your doctor will prescribe you with this medicine only when other medicines in the same group have not helped you.

Therapeutic group:

Non-Steroidal Anti-Inflammatory Drug (NSAID)

2. Before using this medicine

Do not use this medicine if:

- you are allergic to the active ingredient or to any of the other active ingredients in this medicine (listed in section 6).
- you previously had any allergic reaction and/or skin reactions, regardless of severity, such as erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis, after taking other medicines, other NSAIDs, or medicines containing the same active substance.
- you have had symptoms of angioedema, asthma, rash, nasal polyposis or rhinitis due to the use of NSAIDs or acetylsalicylic acid (aspirin).
- you are taking other NSAIDs or acetylsalicylic acid (aspirin) to relieve pain.
- you currently have a stomach and/or duodenal ulcer, or you have digestion problems (dyspepsia) or stomach inflammation (gastritis).
- you have had intestinal or stomach ulcer, bleeding, or perforation (including blood in vomit or in stools or black, tarry stools).
- you have an inflammation or bleeding in the stomach or intestines even if caused by diseases such as gastrointestinal cancer, diverticulitis, ulcerative colitis, Crohn's disease.
- you have a severe liver or kidney disease.
- you have high blood pressure or serious heart problems (moderate to severe heart failure).
- you have a tendency to bleed frequently or severe coagulation problems, or if you are taking blood thinners (anticoagulants).
- you are pregnant or think you may be pregnant or if you are breastfeeding (see the section "Pregnancy, breastfeeding, and fertility").
- you are under 18 years old.

Special warnings about using this medicine**• Before taking BREXIN tell your doctor if:**

- you are elderly (especially if you are over 70 years old) because you have a higher chance of getting side effects from this medicine.
- you are asthmatic or subject to asthma attacks.
- you have eye problems.
- you have diabetes.
- you have kidney problems.
- you have liver problems.
- you have heart or blood vessel problems like heart attack, stroke or congestive heart failure or you think you may be at risk of any of these conditions (if, for example, you have high blood pressure or diabetes or you are a smoker), because medicines like BREXIN may slightly increase the risk of heart attack or stroke.

If you have any of the conditions listed above, consult your doctor who will order additional tests.

Using this medicine in patients older than 80 years is not advisable.

• Like all NSAIDs, this medicine may cause:

- severe or even fatal bleeding, ulcers and perforation in the stomach and intestines at any time, with or without warning signs, even if you have no history of serious conditions of this type.
- in rare cases, serious and in some cases, fatal skin reactions that include reddening, blisters or skin peeling (for example Stevens-Johnson syndrome and toxic epidermal necrolysis). The risk is higher in the earlier stages of treatment.

The risk of having side effects increases with high doses and prolonged use. Follow your doctor's instructions carefully.

- **STOP** your treatment and contact your doctor:
 - if you experience any symptom in your stomach and intestines, especially in the case of bleeding;
 - if you notice any change in your skin (rash), sores in mucous membranes or any other sign of allergic reaction (reddening, itching, swelling of face or throat with breathing difficulties, sudden fall in blood pressure).
- BREXIN may interfere with the results of certain blood tests, for example clotting time. Always tell your doctor that you are taking BREXIN in these cases.

Children and adolescents

Children and adolescents under 18 years old **must NOT** take BREXIN.

Other medicines and BREXIN

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines containing cortisone (corticosteroids)
- blood thinners (anticoagulants or platelet antiaggregating medicines) such as warfarin or aspirin (acetylsalicylic acid)
- medicines for high blood pressure such as diuretics, ACE inhibitors, and angiotensin II antagonists
- medicines containing potassium
- medicines known as 'selective serotonin reuptake inhibitors' (SSRIs), used to treat depression
- other NSAIDs or salicylates or acetylsalicylic acid (aspirin) to relieve pain
- lithium as an anti-depressant
- cimetidine, used to treat stomach ulcers
- quinolone antibiotics used to treat bacterial infections
- if you are using any intrauterine device
- cyclosporin and tacrolimus, medicines that reduce immune system activity

Using this medicine and food

This medicine can be taken with or without food.

Using this medicine and alcohol consumption

It is advisable not to consume alcohol during treatment with this medicine.

Pregnancy, breastfeeding, and fertility

Do not use BREXIN if you are pregnant or think you may be pregnant as it may damage the heart, lungs or kidneys of your unborn baby or cause complications during delivery.

This medication has potential side effect of kidney damage in an unborn baby and low amniotic fluid level beginning in Week 20 of pregnancy. It is advisable to refrain from using medications in the NSAID family as of Week 20 of pregnancy and to consult your healthcare provider if necessary.

Do not use BREXIN when breastfeeding.

This medicine may impair fertility. If you have fertility problems and are taking BREXIN, stop using it.

If you are pregnant, think you may be pregnant or plan to become pregnant, or if you are breastfeeding, you may only use BREXIN if there is a real need for it and under your doctor's supervision. Ask your doctor for advice before taking this medicine

Driving and using machines

This medicine may cause dizziness or unusual tiredness, pay particular attention when driving or operating dangerous machinery.

Important information about some of this medicine's ingredients

This medicine contains lactose monohydrate. If you have been told by a doctor that you have an intolerance to certain sugars, consult your doctor before you start taking this medicine.

This medicine contains less than 1 mmol (23mg) of sodium per tablet, so it is considered sodium-free.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually: 1 tablet once a day.

Your doctor may prescribe a lower dose or another drug to protect your stomach, especially if you are over 70 years old.

The maximum dose is 1 tablet once a day.

Do not exceed the recommended dose!

Taking this medicine: Take the tablet with a glass of water. The score on the tablet is intended to ease splitting and swallowing it and not so that it can be divided into two equal parts. To make it easier to swallow, you may, if necessary, split the tablet immediately before taking it. Swallow both halves together immediately after you have split the tablet. To split the tablet, put it on a flat surface with the score facing upward. Press gently with your thumb to break the tablet into two parts.



There is no information about crushing/chewing the tablets.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. You may experience vomiting, drowsiness, fainting, dizziness, headache.

If you forget to take the medicine at the scheduled time, do not take a double dose to compensate for the missed dose. Take the next dose at the usual time and consult your doctor if you have further questions about using this medicine.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using BREXIN may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop treatment with BREXIN immediately and contact your doctor in the following cases:

- serious abdominal pain, bleeding or burning abdominal pain due to stomach or duodenal ulcers;
- sudden, intense pain in the center of the stomach (perforation of the ulcer);
- vomit with blood (hematemesis) or black stools (melaena) together with stomach or intestinal bleeding or excessive fatigue with reduced urination (due to undetected bleeding);
- allergic reactions, including severe ones, with swelling (angioedema) of the face, lips and throat, that may cause difficulty in breathing or swelling of the hands, including serum disease (a hypersensitivity reaction involving the immune system which usually manifests with fever, rash, and inflamed and painful joints);
- sudden drop in blood pressure (shock) that may cause confusion, increase of heart rate, paleness, fatigue or weakness, or breathing difficulty (warning symptoms);
- serious skin reactions such as blisters, reddening or skin peeling (for example Stevens-Johnson syndrome and toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme).

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

decrease in red blood cells (anemia); headache; vertigo, tinnitus (ringing in the ears); abdominal discomfort or pain, constipation, diarrhea, gas (flatulence), stomach pain or discomfort, nausea, vomiting, indigestion; skin rashes, itching.

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

dizziness; drowsiness; blurred vision; inflammation of mouth with ulcers (ulcerative stomatitis).

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

reduced level of blood hemoglobin due to a fall in the production of red blood cells by the bone marrow (aplastic anemia); reduced level of blood hemoglobin due to production of antibodies that destroy red blood cells (hemolytic anemia); decrease in number of platelets (thrombocytopenia), decrease in number of white blood cells (leukopenia), increase in eosinophil white blood cells (eosinophilia), decrease in number of red and white blood cells and platelets (pancytopenia); swelling (edema) of face and hands due to allergic reactions; vision impairment; yellowing of the skin or eyes (jaundice); fatal inflammation of the liver (fatal hepatitis); skin sensitivity to sunlight (photosensitization of the skin), urticaria; reddening of the skin due to blood leaking from small blood vessels (non-thrombocytopenic purpura); Henoch-Schonlein purpura (inflammation that affects the blood vessels of the skin, bowel and kidneys); inflammation of the kidneys (interstitial nephritis), severe kidney impairment (renal papillary necrosis, nephrotic syndrome); swelling (edema); increase in liver function indexes.

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

bladder problems.

Side effects of unknown frequency (the frequency of these effects has not been established yet)

fluid retention; increase or decrease in blood sugar levels (hyperglycemia, hypoglycemia); abnormal weight gain; depression, strange dreams, hallucinations, sleeping problems (insomnia), confusion, mood swings, nervousness, increased excitability; impaired hearing; inflammation of blood vessels (vasculitis); narrowing of bronchi (bronchospasm); nose bleeding (epistaxis); stomach inflammation (gastritis); pancreas inflammation (pancreatitis); mouth dryness; liver inflammation (hepatitis); hair loss (alopecia); peeling skin; bruises (ecchymosis); excessive sweating; abnormal nail growth; blood in the urine (hematuria), difficulty urinating (dysuria); malaise, fatigue; lack of or reduced appetite (anorexia); abnormal blood indices (decrease in hemoglobin or hematocrit, increased transaminase levels, positive test for antinuclear antibody); exacerbation of inflammation of the colon (colitis) and Crohn's disease; changes in kidney function (acute renal failure); increase in blood pressure, reduced function of the heart (cardiovascular diseases).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

lactose monohydrate, crospovidone, sodium starch glycolate, colloidal hydrated silica, pregelatinized starch, magnesium stearate.

What the medicine looks like and contents of the pack:

Light yellow, hexagonal tablet with score line.

This medicine is available in blister packages of 4, 10, 20, and 30 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14
Hakitor Street, Haifa Bay, 2624761

Manufacturer's name and address: Chiesi Farmaceutici S.P.A., via Palermo 26/A, Parma,
Italy

Revised in June 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
136-61-29695-00