**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

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

**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?

For symptomatic relief of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis. Your doctor will prescribe this medicine for you only after failure of treatment with another non-steroidal anti-inflammatory drug (NSAID).

**Therapeutic group:** Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

## 2. Before using this medicine

### Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other 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 or toxic epidermal necrolysis, after taking other medicines, including other NSAIDs, or medicines containing the same active substance.
- You have had symptoms of angioedema, asthma, rash, nasal polyps 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 (gastrointestinal), even if caused by diseases such as stomach or intestinal cancer, diverticulitis, ulcerative colitis, Crohn's disease.
- You have a severe liver or kidney disease.
- You have high blood pressure (severe hypertension) or serious heart problems (moderate to severe heart failure).
- You have a tendency to bleed frequently, for example you have 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 section 'Pregnancy, breastfeeding, and fertility').

**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 problems digesting BREXIN, that is your body has few enzymes that break down the medicine.
  - 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, diabetes, high cholesterol 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.

**Pay attention, since during treatment with any NSAID:**

- At any time, with or without warning signs, even if you have no history of severe abdominal or intestinal problems, bleeding, ulcers or perforation of the stomach and intestines can occur, which may cause death.
- In very rare cases, severe, and in some cases fatal skin reactions that include reddening, blisters or skin peeling (for example Stevens-Johnson syndrome and toxic epidermal necrolysis) may occur. The risk is higher in the earlier stages of treatment.
- If you develop a rash or notice any symptoms on your skin, you must immediately stop taking BREXIN and contact a doctor immediately, informing him/her that you are taking BREXIN.

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 the stomach, liver and intestines, especially in the case of bleeding;
  - if you notice any change in the skin (rash), sores in mucous membranes or any other sign of allergic reaction (such as reddening, itching, swelling of face or throat with breathing difficulties, sudden fall in blood pressure).
  - if there are changes in the blood tests that assess liver function.
- BREXIN may interfere with the results of certain blood tests, for example clotting time and eosinophil count. In such case, contact your doctor and tell him that you are taking BREXIN.

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

**Interactions with other medicines**
**If you are taking or have recently taken other medicines, including nonprescription medicines 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 acetylsalicylic acid (aspirin)
- medicines for high blood pressure such as diuretics, ACE inhibitors, angiotensin II antagonists or beta blockers
- medicines containing potassium
- antidepressants known as 'selective serotonin reuptake inhibitors' (SSRIs)
- other NSAIDs or salicylates or acetylsalicylic acid (aspirin) to relieve pain
- lithium to treat depression
- cimetidine to treat stomach ulcers
- quinolone antibiotics to treat bacterial infections
- if you are using any intrauterine device
- cyclosporin and tacrolimus, medicines that reduce immune system activity
- methotrexate to treat rheumatoid arthritis, psoriasis, Crohn's disease and some cancers
- beta-blockers - medicines used for blood pressure lowering, heart failure, after a heart attack, in angina pectoris and in migraine prophylaxis.

**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**
Pregnancy
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 medicine has a potential side effect of kidney damage in an unborn baby and low amniotic fluid level beginning from week 20 of pregnancy. It is advisable to refrain from using medicines of the NSAID family starting from week 20 of pregnancy and to consult your healthcare provider if necessary.
Breastfeeding
Do not use BREXIN when breastfeeding.
Fertility
This medicine may impair fertility. If you have fertility problems and are taking BREXIN, stop using it.

**Driving and using machines**

This medicine may cause dizziness or unusual tiredness. Take special care when driving or operating dangerous machinery.

**Important information about some of this medicine's ingredients**
This medicine contains lactose. 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) 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 dosage or another drug to protect your stomach, especially if you are over 70 years old.
The maximum dosage 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. 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, dizziness, fainting, drowsiness, 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

As with any medicine, 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 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 upper abdomen (perforation of the ulcer);
- vomit with blood (hematemesis) or black stools (melena) resulting from stomach or intestinal bleeding or excessive fatigue with reduced urination (due to undetected bleeding);
- allergic reactions, including severe ones (anaphylaxis), 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, 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, toxic epidermal necrolysis, exfoliative dermatitis (erythroderma), 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 rash, 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 decrease 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 the 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-Schönlein 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)
urinary 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); nosebleed (epistaxis); stomach inflammation (gastritis); pancreas inflammation (pancreatitis); mouth dryness; liver inflammation (hepatitis); hair loss (alopecia); peeling skin; bruises (ecchymosis); fixed drug eruption (it may appear in the form of round or oval patches of redness and swelling of the skin); blisters (urticaria), itching; sweating; abnormal nail growth; blood in the urine (hematuria), difficulty urinating (dysuria); malaise, fatigue; lack of or reduced appetite (anorexia); weight gain; abnormal blood indices (decrease in hemoglobin or hematocrit, increased transaminase levels, positive test for antinuclear antibodies); exacerbation of inflammation of the colon (colitis) and Crohn's disease; changes in kidney function (acute renal failure); fluid accumulation; increase in blood pressure, reduced function of the heart (heart failure, cardiovascular diseases); heart attack; stroke; female infertility.

**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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or 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 glycollate, colloidal hydrated silica, pregelatinized starch, magnesium stearate.

**What the medicine looks like and contents of the pack:**
Light yellow, hexagonal tablet with a 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 September 2023 according to MOH guidelines.

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