

BLOOMS THE CHEMIST ANTI-INFLAMMATORY PAIN RELIEF TABLETS

diclofenac sodium

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief is used for

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief Tablets belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat pain and reduce inflammation (swelling and redness).

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief Tablets is used to treat pain associated with:

- painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (e.g. tennis elbow)
- menstrual cramps (period pain)

It can relieve the symptoms of pain and inflammation but it will not cure your condition.

Ask your doctor if you have any questions about this medicine

This medicine is not addictive.

Before you use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief

When you must not use it

Do not use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief if you are allergic (hypersensitive) to:

- diclofenac (the active ingredient in BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief) or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac
- aspirin
- ibuprofen
- any other NSAID

If you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or

NSAID medicines. If you are allergic to aspirin or NSAID medicines and you use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief, these symptoms may be severe.

Do not use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief if you have had any of the following medical conditions:

- a stomach or intestinal ulcer
- bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- kidney or liver problems
- severe heart failure
- heart bypass surgery

Do not use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief during the first 6 months of pregnancy, except on doctor's advice. Do not use during the last three months of pregnancy.

Use of this medicine during the last 3 months of pregnancy may affect your baby and may delay labour and birth.

Use of non-aspirin NSAIDs can increase the risk of miscarriage, particularly when taken close to the time of conception.

Do not use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have any of the following health problems / medical conditions:

- established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, peripheral arterial disease or atherosclerotic cardiovascular disease), as treatment with BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief is generally not recommended
- established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- a past history of ulcers (stomach or intestinal)
- gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative colitis)
- past history of haemorrhoids (piles) or irritation of the rectum (back passage)
- liver or kidney problems
- a rare liver condition called porphyria
- bleeding disorders or other blood disorders (e.g. anaemia)

- asthma or any other chronic lung disease that causes difficulty in breathing
- hay fever (seasonal allergic rhinitis)
- repeated chest infections
- polyps in the nose
- diabetes
- dehydration (e.g. by sickness, diarrhoea, before or after recent major surgery)
- swollen feet

Your doctor may want to take special precautions if you have any of the above conditions.

It is generally important to take the lowest dose of BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.

Tell your doctor if you are pregnant or trying to become pregnant.

There is not enough information to recommend the use of BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief Tablets during the first 6 months of pregnancy and it must not be used during the last 3 months. BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief may also reduce fertility and affect your chances of becoming pregnant. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you currently have an infection.

If you use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief while you have an infection, some of the signs of the infection such as pain, fever, swelling and redness may be hidden. You may think, mistakenly, that you are better or that the infection is not serious.

Tell your doctor if you are breast-feeding.

Breast-feeding is not recommended while you are using this medicine. The active ingredient in BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief passes into breast milk and may affect your baby.

Tell your doctor if you are lactose intolerant.

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief tablets contain lactose.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies, especially if you get skin reactions with redness, itching or rash.

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.

Some medicines that are important to mention include:

- other anti-inflammatory medicines, e.g. aspirin, salicylates or ibuprofen
- warfarin or other "blood thinners" (medicines used to prevent blood clotting)
- digoxin (a medicine for heart problems)
- lithium or selective serotonin- reuptake inhibitors (SSRIs), a medicine used to treat some types of depression
- diuretics (medicines used to increase the amount of urine)

- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure, heart conditions, glaucoma and migraine)
- prednisone, cortisone, or other corticosteroids (medicines used to provide relief for inflamed areas of the body)
- medicines used to treat diabetes, except insulin
- methotrexate (a medicine used to treat arthritis and some cancers)
- cyclosporin, tacrolimus (a medicine used in patients who have received organ transplants)
- trimethoprim (a medicine used to prevent or treat urinary tract infections)
- some medicines used to treat infection (quinolone antibacterials)
- glucocorticoid medicines, used to treat arthritis
- sulfapyrazone (a medicine used to treat gout)
- voriconazole (a medicine used to treat fungal infections)
- phenytoin (a medicine used to treat seizures)
- the Rifampicin (an antibiotic medicine used to treat bacterial infections)

You may need to take different amounts of your medicines or to take different medicines while you are using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start using this medicine.

How to use BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

When to take it

Take BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief Tablets with or immediately after a meal.

If you take them on an empty stomach, it may cause stomach upset.

How much BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief to take/ use

Adults: The usual dosage is one or two tablets two or three times a day when necessary. **Do not take more than eight tablets in 24 hours.**

Not recommended for use in children.

Do not exceed the recommended dose.

How to take the tablets

Swallow the tablets whole with a full glass of water or other liquid. Do not chew them.

The tablets have a special coating to keep them from dissolving until they have passed through the stomach into the bowel. Chewing the tablets would destroy the coating.

How long to take/use it

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief tablets are for short term use only. If pain persists for more than 3 days, please see your doctor.

If you forget to take/use it

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief tablets should only

be taken when necessary. It should not be taken on a regular basis.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you take/use too much BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

If you take too much BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief, you may experience:

- vomiting
- bleeding from the stomach or bowel
- diarrhoea
- dizziness
- ringing in the ears
- convulsions (fits)

While you are taking/ using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief

Things you must do

If you become pregnant whilst taking or using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief, tell your doctor immediately.

Your doctor can discuss with you the risks of using it while you are pregnant.

If, at any time while taking BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately. These may be signs of cardiovascular toxicity.

If you are going to have surgery, make sure the surgeon and anaesthetist know that you are using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief.

NSAID medicines can slow down blood clotting and affect kidney function.

If you get an infection while using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief, tell your doctor.

This medicine may hide some of the signs of an infection (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief.

Tell any other doctor, dentist or pharmacist who treats you that you are using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief.

Things you must not do

Do not take any of the following medicines while you are using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief without first telling your doctor:

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates
- other medicines containing diclofenac
- ibuprofen
- any other NSAID medicine

If you take these medicines together with BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief, they may cause unwanted side effects.

If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, your doctor or pharmacist can advise you.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief affects you.

This medicine may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If you have any of these symptoms, do not drive, use machines, or do anything else that could be dangerous.

Elderly patients should take the minimum number of tablets that provides relief of symptoms.

Elderly patients may be more sensitive to the effects of BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief than other adults.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, indigestion, cramps, loss of appetite, wind
- heartburn or pain behind or below the breastbone (possible symptoms of an ulcer in the tube that carries food from the throat to the stomach)
- stomach or abdominal pain
- constipation, diarrhoea
- sore mouth or tongue
- altered taste sensation
- headache
- dizziness, spinning sensation
- drowsiness, disorientation, forgetfulness
- feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods

- shakiness, sleeplessness, nightmares
- tingling or numbness of the hands or feet
- feeling of fast or irregular heart beat
- unusual weight gain or swelling of arms, hands, feet, ankles or legs due to fluid build-up
- symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth, and/or skin) that happen more quickly than normal
- skin inflammation with flaking or peeling
- vision disorders* (e.g. blurred or double vision)
- buzzing or ringing in the ears, difficulty hearing
- hypertension (high blood pressure)
- hair loss or thinning

NSAIDs, including diclofenac, may be associated with increased risk of gastrointestinal anastomotic leak. Close medical surveillance and caution are recommended when using this medicine after gastrointestinal surgery.

***If symptoms of vision disorders occur during treatment with this medicine, contact your doctor as an eye examination may be considered to exclude other causes.**

If any of the following signs appear, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- red or purple skin (possible signs of blood vessel inflammation)
- severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (possible stomach problems)
- rash, skin rash with blisters, itching or hives on the skin; swelling of the face, lips, mouth, tongue, throat, or other part of the body which may cause difficulty to swallow, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)
- wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma)
- yellowing of the skin and/or eyes (signs of hepatitis/liver failure)
- persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems)
- constant "flu-like" symptoms including chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy, bleeding or bruising more easily than normal (possible blood problem)
- painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals, which may be accompanied by fever and chills, aching muscles and feeling generally unwell (possible serious skin reaction)
- signs of a possible effect on the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty in speaking, paralysis (signs of cerebral attack), convulsions (fits)
- change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood or excess

of protein in the urine (possible kidney disorders)

- sudden and oppressive chest pain (which may be a sign of myocardial infarction or a heart attack)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- Coincidental occurrence of chestpain and allergic reactions (signs of Kounis syndrome)

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief

Storage

Keep your medicine in the original container until it is time to use it.

- Store it in a cool dry place.
- Do not store BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief Tablets or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

BLOOMS THE CHEMIST ANTI-INFLAMMATORY PAIN RELIEF tablets are round, pale yellow, enteric coated tablets plain on both sides blisters of 10, 20 or 30*.

* not all pack sizes may be marketed

Ingredients

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief tablets

Contain 25mg diclofenac sodium as the active ingredient in gastro-resistant tablets.

The tablets also contain:

- colloidal anhydrous silica
- cellulose microcrystalline
- lactose monohydrate
- magnesium stearate
- maize starch
- povidone
- hypromellose
- iron oxide yellow
- titanium dioxide
- sodium starch glycollate A
- purified talc
- PEG-40
- hydrogenated castor oil
- EUDRAGIT L30D-55 (PI 3700)
- triethyl citrate

This medicine contains sugars as lactose. It may also contain a trace amount of sulfites.

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

BLOOMS THE CHEMIST Anti-Inflammatory Pain Relief is supplied in Australia by:

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
AUSTRALIA

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