

DYNASTAT[®]

(die-na-stat)

parecoxib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dynastat powder for injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or nurse.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Dynastat against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Dynastat is used for

What Dynastat is for

This medicine is used for the prevention and treatment of pain. It can be used to relieve pain and reduce inflammation (swelling and soreness) which may occur after surgery.

Although Dynastat can relieve the symptoms of pain and inflammation, it will not cure your condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

How Dynastat works

This medicine belongs to a group of medicines called Coxibs.

These medicines work by relieving pain and inflammation.

Using Dynastat

Dynastat is an injection. Only a doctor or nurse can give the injection.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you are given Dynastat

When it must not be used

You must not be given Dynastat if you have an allergy to:

- parecoxib sodium or valdecoxib
- any of the ingredients listed at the end of this leaflet
- sulphonamides, a group of medicines which include, for example, certain antibiotics (if you are not sure whether you are taking one of these medicines ask your doctor or nurse).

Some of the symptoms of an allergic reaction to Dynastat may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- swelling, blistering or peeling of the skin.

These symptoms may be severe if you are allergic to sulphonamides or to any of the ingredients listed at the end of this leaflet and you are given Dynastat.

Ask your doctor or nurse if any of this applies to you.

You must not be given Dynastat if you have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to treat pain and inflammation), including other Coxib medicines.

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

If you are not sure if you are taking any of these medicines, ask your doctor or nurse.

If you are allergic to aspirin or NSAIDs, including other Coxib medicines and use Dynastat, these symptoms may be severe.

You must not be given Dynastat if you are about to undergo heart or blood vessel surgery.

You should not be given Dynastat if you have had any of the following medical conditions. Your doctor or nurse need to know if you have ever had:

- heart disease
- a heart attack
- a stroke

- severe liver problems.

You must not be given Dynastat if you are in the third trimester of your pregnancy or are breastfeeding.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Your doctor and nurse need to know if you have any allergies to:

- any other medicines including aspirin or other NSAID medicines, including other Coxib medicines
- any other substances, such as foods, preservatives or dyes.

Your doctor and nurse need to know about all your medical conditions, especially if you have ever had any of the following:

- kidney or liver problems
- heart problems, heart surgery, heart failure, heart attack or other blood vessel disease
- stroke
- diabetes
- high cholesterol levels
- high blood pressure

- fluid retention or if you are receiving diuretic treatment
- dehydration
- asthma or other allergic conditions
- skin problems with symptoms such as swelling, blistering, peeling, itching, reddening or some other abnormality
- peptic ulcer i.e. stomach or duodenal ulcer.

Your doctor and nurse need to know if you are pregnant or intend to become pregnant.

You should not be treated with Dynastat if you are in the third trimester of your pregnancy.

Treatment with Dynastat during the first two trimesters of your pregnancy is not recommend as it may affect your developing baby. It may also affect your labour. Your doctor will discuss with you the benefits and risks of treatment with Dynastat.

Related medicines, NSAIDs, have been associated with reversible infertility in some women.

Treatment with NSAIDS in early pregnancy can increase the risk of spontaneous abortion and may affect your developing baby.

Treatment with NSAIDs in the second or third trimester of your pregnancy may cause kidney problems in your developing baby.

Your doctor will discuss with you the benefits and risks of treatment with Dynastat.

Your doctor and nurse need to know if you are breastfeeding or intend to breastfeed.

You should not be given Dynastat if you are breastfeeding.

Dynastat passes into breast milk, therefore, breastfeeding should be discontinued during treatment with Dynastat.

Your doctor and nurse need to know if you are a smoker or drink alcohol.

Your doctor and nurse need to know if you currently have an infection.

If you are given Dynastat while you have an infection, it may hide some of the signs of an infection.

If you have not told your doctor and nurse about any of the above, tell them before you are given Dynastat.

Taking other medicines

Some medicines may be affected by Dynastat or may affect how well it works. Your doctor may need to give you different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and nurse need to know if you are taking any other medicines, including:

- all prescription medicines
- all medicine bought over-the-counter from a pharmacy or supermarket
- all complementary and alternative therapies
- any supplements or herbal remedies bought from a health food shop.

Your doctor and nurse need to know if you are taking any medicines used to treat high blood pressure or other heart problems. These include ACE inhibitors, angiotensin receptor antagonists, beta blockers and diuretics (also called fluid or water tablets).

These medicines can cause kidney problems if taken at the same time as you receive Dynastat.

Your doctor and nurse need to know if you are taking any of the following:

- aspirin, salicylates or other NSAID medicines used to treat pain, inflammation or swelling
- corticosteroids, medicines used to suppress the immune system or reduce inflammation
- selective serotonin reuptake inhibitors, medicines used for depression
- warfarin or similar medicines including Eliquis (apixaban), Xarelto (rivaroxaban), Pradaxa (dabigatran) or

antiplatelet medicines that are used to prevent or stop blood clots from forming

- lithium, a medicine used to treat some types of depression
- some medicines used to treat diabetes
- methotrexate, a medicine used to treat arthritis and some cancers
- ciclosporin, a medicine used to suppress the immune system
- fluconazole and ketoconazole used to treat fungal infections.

Your doctor and nurse have more information on medicines to be careful with or avoid while using Dynastat.

How Dynastat is given

Your doctor will decide how much Dynastat you need. The usual recommended dose is a single 40 mg injection. Your doctor may adjust the dosage you are given depending on your condition.

Dynastat will be given to you by your doctor. It is diluted and given by injection into a vein through an intravenous line or into a muscle.

Ask your doctor if you want more information about the dose of Dynastat and how it is given.

If you receive too much (overdose)

As your doctor will supervise how much Dynastat you are given, you are unlikely to have an overdose.

If you are given too much Dynastat, you may feel tired, drowsy or sick, or you may be sick, have stomach pains or other abdominal problems.

If you think you have been given too much Dynastat:

- tell your doctor or nurse immediately, or
- telephone the Poisons Information Centre (telephone 131 126).

While you are receiving Dynastat

Things you must not do

Do not take any other medication unless your doctor is aware of it.

Things to be careful of

Be careful driving or operating machinery after your surgery in case Dynastat has affected you.

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving Dynastat.

This medicine has been prescribed to help you, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

Other side effects not listed below may also occur in some people.

Tell your doctor...

The following list shows common side effects of Dynastat.

Tell your doctor or nurse if you notice any of the following physical problems and they worry you:

- changes in blood pressure
- dizziness or light-headedness due to low blood pressure
- back pain

- ear ache
- feeling numb (your skin may lose sensitivity to pain and touch)
- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- constipation, diarrhoea, pain in the stomach, wind, bloating
- dizziness
- sore throat
- swollen and sore gums
- increased sweating
- passing less urine than normal
- inflammation and pain after a tooth extraction.

Tell your doctor or nurse if you notice any of the following mental or emotional problems and they worry you:

- trouble sleeping
- irritability, agitation.

Tell your doctor immediately if...

The following list includes serious side effects which may require medical attention.

Do not be alarmed as you may not experience any of them.

Tell your doctor or nurse immediately if you notice:

- a skin rash, including hives, raised red, itchy spots
- blistering and bleeding in the lips, eyes, mouth, nose and genitals
- swelling, blistering or peeling of the skin, which may be accompanied by fever, chills, headache, sore throat, diarrhoea, aching joints and muscles
- swollen glands e.g. under armpit or neck
- any other signs of allergic reaction such as wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- a slow heart beat
- a severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- any signs of anaemia, such as tiredness, being short of breath, and looking pale
- an unusual weight gain or loss of appetite
- unusual stomach sounds

- swelling of lips and tongue
- severe stomach or throat pain
- joint pain, muscle weakness
- you are vomiting blood or having black sticky bowel motions
- any infection of, or discharge from, any wounds
- complications with skin healing after operations
- injection site pain or reaction
- yellowing of the skin or eyes (jaundice)
- a dry mouth, feeling of thirst and needing to urinate more often
- feeling faint or collapse, have shortness of breath, feel tired
- have irregular heartbeat, chest pain or discomfort, swollen or sore leg veins.

Product Description

What it looks like

Dynastat is supplied to the hospital in single-use glass vials, and requires dilution with normal saline before use.

It is a white to off-white powder.

When diluted, Dynastat is a clear and colourless solution.

Ingredients

The active ingredient in Dynastat is parecoxib (as parecoxib sodium).

Dynastat contains 40 mg parecoxib per vial.

Dynastat also contains dibasic sodium phosphate, phosphoric acid and sodium hydroxide.

Australian registration numbers

Dynastat 40 mg - AUST R 82525.

Supplier

Dynastat is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney, NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au.

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