

DYNASTAT®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with Dynastat?

Dynastat contains the active ingredient parecoxib sodium. Dynastat is used to relieve pain and reduce swelling and soreness which may occur after surgery. For more information, see Section [1. Why am I being treated with Dynastat?](#) in the full CMI.

2. What should I know before treatment with Dynastat?

You must not be given Dynastat if you: have ever had an allergic reaction to parecoxib or any ingredients listed at the end of the CMI, take other medicines to relieve pain, reduce swelling and soreness or sulfonamides antibiotics; are about to have heart or blood vessel surgery, have had heart or other blood vessel disease, stroke, severe liver problems or in the third trimester of pregnancy or are breastfeeding. Tell your doctor if you have or ever had kidney or liver problems, heart diseases, other blood vessel diseases or taking

medicines for these conditions, stroke, diabetes, high cholesterol, high or low blood pressure, water retention or taking “water” tablets, dehydrated, asthma, blood clots or taking medicine for blood clots, swelling, blistering, peeling, itching, reddening or some other skin problems after taking similar medicines, stomach ulcers or bloody or black stools, smoke, have a fever or an infection. For more information, see Section [2. What should I know before I treatment with Dynastat?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dynastat and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Dynastat given?

Dynastat is given by a doctor or nurse. Your doctor will decide how much Dynastat you will need. More instructions can be found in Section [4. How Dynastat will be given to me?](#) in the full CMI.

5. What should I know during treatment with Dynastat?

Things you should do	Tell your doctor if you are pregnant, intend to become pregnant, breastfeeding or intend
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	to breastfeed. Tell your doctor if you develop allergic reactions such as extensive skin rashes, severe blisters and bleeding in lips, eyes, mouth, nose and genitals.
Things you should not do	Do not withhold your medical history including current medicines or supplements used from your doctor. Do not take any other medicines unless your doctor is aware of it.
Driving or using machines	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.
Drinking alcohol	Tell your doctor or nurse if you drink alcohol.

For more information, see Section [5. What should I know during treatment with Dynastat?](#) in the full CMI.

6. Are there any side effects?

Side effects: allergic reaction, e.g., wheezing, swollen face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; skin rash, swelling/blistering/peeling; bruises; red, purple blotches; blisters/bleeding lips, eyes, mouth, nose, genitals; swollen armpit, neck or limbs; injection site pain/reaction; fever; chills; delayed wound healing; wound discharges; pain after tooth extraction; yellow skin/eyes; back, joint pain; weak muscle; earache; tiredness; pale looking skin; slow or irregular heartbeat; low/high blood pressure; dizziness; fainting; shortness of breath; chest, neck or shoulder pain; swollen, sore leg veins; severe, persistent headache, stiff neck, light sensitivity; weight gain; appetite loss; diarrhoea; unusual stomach sounds; severe stomach pain; sore throat; vomiting; bloody/black stool; heartburn; constipation; wind, bloating; dry mouth, feeling thirsty; urinate often; pass less urine; trouble sleeping; irritability; agitation; skin becomes numb or painful to touch; increased sweating; liver, kidney or heart problems; and blood sugar, calcium or potassium changes. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DYNASTAT® (die-na-stat)

Active ingredient(s): *parecoxib sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dynastat. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dynastat.**

Where to find information in this leaflet:

- [1. Why am I being treated with Dynastat?](#)
- [2. What should I know before treatment with Dynastat?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Dynastat given?](#)
- [5. What should I know during treatment with Dynastat?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with Dynastat?

Dynastat contains the active ingredient parecoxib sodium. Dynastat is a type of non-steroidal anti-inflammatory drug (NSAID) and belongs to a group of medicines called Coxibs. Dynastat is used to relieve pain and reduce swelling and soreness, which may occur after surgery.

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.

2. What should I know before treatment with Dynastat?

Warnings

You must not be given Dynastat if you are allergic to or have experienced allergic reactions to:

- parecoxib or any of the ingredients listed at the end of this leaflet
- other Coxib medicines, such as valdecoxib, celecoxib
- aspirin, ibuprofen or other NSAIDs used to treat pain, swelling and soreness
- sulfonamides, a type of antibiotic.

You must not be given Dynastat if you have or had any of the following medical conditions:

- heart or blood vessel surgery
- heart problems, heart failure, heart attack or other blood vessel disease
- a stroke
- severe liver problems.
- in the third trimester of your pregnancy or are breastfeeding

Tell your doctor if you have ever had any of the following:

- kidney or liver problems
- heart or blood vessel surgery, heart problems, heart failure, heart attack or other blood vessel disease or taking medicines for any of these conditions
- stroke
- diabetes
- high cholesterol
- high or low blood pressure
- blood clots or taking medicine to prevent blood clots
- smoke
- water retention or taking “water” tablets
- feeling dehydrated
- asthma or other allergic conditions
- skin problems such as swelling, blistering, peeling, itching or redness that can occur with fever chills, headache, joint pain or generally feeling unwell, or some other skin abnormality after taking NSAIDs or other Coxib medicines
- stomach ulcers or bloody or black stools
- fever or an infection. If you are given Dynastat when you have an infection, it may hide a fever (a sign of an infection).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor and nurse 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.

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

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

Use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion and may affect your developing baby.

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

Tell your doctor and nurse if you are breastfeeding or intend to breastfeed.

You should not be treated with Dynastat if you are breastfeeding.

Dynastat passes into breast milk, therefore, you need to stop breastfeeding during treatment with Dynastat.

Children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Dynastat and affect how it works. These include medicines for:

- high blood pressure (e.g., losartan, olmersartan), other heart diseases (e.g., captopril, enalapril, monopril, lisinopril, accupril, ramipril, fluid or “water” tablets, (e.g., hydrochlorothiazide, indapamide), pain, fever and inflammation (e.g., aspirin or other NSAIDs) or combinations of these medicines
- severe allergies, swelling or inflammation such as corticosteroids (e.g., prednisolone)
- preventing or stopping blood clots, e.g., warfarin or apixaban, rivaroxaban, dabigatran
- anxiety, depression or prevent mood swings, e.g., lithium salts, fluoxetine or sertraline
- diabetes, e.g., glibenclamide.
- arthritis and cancer, such as methotrexate
- preventing the body from rejecting the new organ after transplants, e.g., ciclosporin, tacrolimus

- fungal infections, e.g., fluconazole and ketoconazole.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dynastat.

4. How is Dynastat given?

How much is given and how it is given

Dynastat will be given to you in the hospital. Your doctor will decide how much Dynastat you need. It may depend on whether you have liver or kidney problems, your age, weight or other medicines you may be taking.

If too much Dynastat is given

As Dynastat is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you experience any side effects tell your doctor or nurse immediately.

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

If you are concerned that you may have been given too much Dynastat, you may need urgent medical attention.

You should immediately:

- tell your doctor or nurse, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with Dynastat?

Things you should do

Tell your doctor if you:

- are pregnant, intend to become pregnant, breast feeding or intend to breastfeed.
- develop sudden potentially life-threatening allergic reactions such as extensive skin rashes, severe blisters and bleeding in lips, eyes, mouth, nose and genitals.

Things you should not do

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

Do not withhold your medical history including current medicines or supplements used from your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dynastat affects 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.

Drinking alcohol

Tell your doctor or nurse if you drink alcohol.

Looking after your medicine

Dynastat is stored in a hospital and it is responsible for storing and disposing of any unused product correctly.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• vomiting• heartburn• constipation• diarrhoea	Speak to your doctor if you have any of these side effects and they worry you

Side effects	What to do
<ul style="list-style-type: none"> ● stomach pain, wind, bloating, feeling uncomfortably full ● dry mouth, feeling thirsty and needing to urinate more often ● back pain ● earache ● pain after a tooth extraction ● sore throat ● low or high blood pressure ● dizziness or light-headedness ● trouble sleeping ● irritability, agitation ● feeling numb (your skin may lose sensitivity to pain and touch) ● increased sweating ● passing less urine than normal ● loss of appetite ● problems with your liver, kidneys or heart* 	

Side effects	What to do
<ul style="list-style-type: none"> ● changes in your blood sugar, calcium or potassium level* <p>*These side effects may show up when you have a blood test.</p>	

Side effects

Side effects	What to do
<ul style="list-style-type: none"> ● signs of allergic reaction such as wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing ● skin rash including hives, raised red, itchy spots ● swelling, blistering or peeling of skin, fever, chills, headache, sore throat, diarrhoea, aching joints and muscles ● bleeding or bruising more easily than normal, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</p>

Side effects	What to do
<p>reddish or purplish blotches under the skin</p> <ul style="list-style-type: none"> ● complications with skin healing after operations ● yellowing of the skin or eyes (jaundice) ● slow heartbeat ● irregular heartbeat ● unusual weight gain or loss of appetite ● unusual stomach sounds ● severe stomach or throat pain ● vomiting blood or bloody/black sticky bowel motions ● blistering and bleeding in the lips, eyes, mouth, nose and genitals ● swelling under the armpit or neck ● injection site pain or reaction ● joint pain, muscle weakness ● tiredness, short of breath, looking pale 	

Side effects	What to do
<ul style="list-style-type: none"> ● discharge from wounds ● feeling faint or collapse, shortness of breath ● chest pain or discomfort spreading to neck or shoulders, swollen or sore leg veins ● a severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Dynastat contains

Active ingredient (main ingredient)	parecoxib sodium
Other ingredients (inactive ingredients)	dibasic sodium phosphate, phosphoric acid and sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What Dynastat looks like

Dynastat is a white to off-white powder. When diluted, Dynastat is a clear and colourless solution.

Dynastat 40 mg powder for injection - AUST R 82525.

Who distributes Dynastat

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

www.pfizermedinfo.com.au.

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