

EDECIN[®] Tablets

Ethacrynic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EDECIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from www.menarini.com.au

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What EDECIN is used for

EDECIN helps to reduce the amount of fluid in the body for people who have:

- swelling of the ankles, feet and legs, which is called oedema
- fluid accumulation in the lungs, which is called pulmonary oedema

- fluid accumulation in the stomach area (which is also called ascites) due to liver disease

EDECIN is also used in children, over 2 years old, to remove fluid that occurs in some heart and kidney conditions.

EDECIN belongs to a group of medicines called diuretics or fluid tablets.

It works by making your kidneys pass more water and salt from the body.

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.

This medicine is not addictive.

Before you take EDECIN

When you must not take it

Do not take EDECIN if you have an allergy to:

- EDECIN
- any of the ingredients listed at the end of this leaflet.

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

Do not take this medicine if you are pregnant or intend to become pregnant.

Like most medicines, EDECIN is not recommended for use during pregnancy.

Do not take this medicine if you are not passing urine

Do not give this medicine to a child under the age of two years.

Safety and effectiveness in children younger than two years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease
- heart disease

Tell your doctor if you are breast-feeding or plan to breast feed.

Like most medicines, EDECIN is not recommended for use while breast feeding. If it is necessary for you to take EDECIN, your doctor may ask you to stop breast feeding.

If you have not told your doctor about any of the above, tell them before you start taking EDECRIN.

Taking other medicines

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

Some medicines and EDECRIN may interfere with each other. These include:

- medicines used to treat high blood pressure
- certain antibiotics such as aminoglycosides
- warfarin, a medicine used to prevent blood clots
- lithium, a medicine used to treat severe mood swings
- corticosteroids, such as prednisone and cortisone

These medicines may be affected by EDECRIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take EDECRIN

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

They may differ from the information contained in this leaflet.

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.

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

How much to take

For adults, the usual starting dose is two 25mg tablets taken once a day. Depending on your response, your doctor may increase this dose. Most people take between 50 mg and 150 mg per day, which is 2 to 6 tablets per day. If you are taking more than two tablets per day, your dose will be divided into two doses per day.

For children over 2 years of age, the usual starting dose is 25 mg (1 tablet) taken once a day.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

If you take EDECRIN once a day, take it immediately after breakfast.

If you take EDECRIN more than once a day, take your first dose immediately after breakfast and take your last dose no later than 6 p.m., unless your doctor tells you otherwise.

EDECRIN may increase the amount of water (urine) you pass and also the number of times you go to the toilet. By taking the last dose no later than 6 p.m., there may be less chance of your sleep being disturbed.

Follow the above instructions even if you don't take EDECRIN every day.

Your doctor will determine whether or not you need to take EDECRIN every day.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and

take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much EDECRIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many tablets, you will probably feel light-headed, dizzy, or weak, or you may faint. You may also become very thirsty, confused), have a change in the amount of urine passed, have a fast heart beat, have muscle cramps, or feel a tingling sensation of the skin.

While you are using EDECRIN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking EDECRIN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery (even at the dentist's), that needs a general anaesthetic, tell the doctor

or dentist that you are taking this medicine.

Your blood pressure may drop suddenly.

If you become pregnant while taking this medicine, tell your doctor immediately.

Have your blood tested when your doctor says to make sure your potassium and some other substances in the blood known as electrolytes are at the right level.

EDECIN may cause a loss of water, potassium and some other electrolytes from your body. This may cause:

- dry mouth or thirst
- weakness, tiredness, numbness tingling in the hands and/or feet
- muscle pains or cramps,
- restlessness
- irregular or fast heart beat
- passing less urine than normal.

Tell your doctor if you get any of these symptoms.

Your doctor may ask you to take a potassium supplement while taking EDECIN.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take EDECIN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EDECIN.

This medicine helps most people with some types of fluid accumulation, but it may have unwanted side effects in a few 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 lists of side effects. You may not experience any of them.

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

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

- feeling sick, nausea, vomiting, loss of appetite
- generally feeling unwell
- headache, tiredness, weakness
- stomach upset or pain, diarrhoea
- dry mouth or thirst
- muscle pains or cramps,
- restlessness
- passing less urine than normal
- ringing in the ears
- blurred vision

These are usually mild effects, but may be serious.

Tell your doctor as soon as possible if you notice any of the following:

- irregular or fast heart beat
- yellowing of the skin and eyes, which is also called jaundice
- difficulty in swallowing
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bruising more easily than normal
- spinning sensation, which is also called vertigo
- numbness or tingling in the hands and/or feet
- feeling anxious or confused
- skin rash
- blood in the urine

These are serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Emergency at your nearest hospital if any of the following happen:

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black, sticky bowel motions (stools) or bloody diarrhoea
- severe pain or tenderness in any part of the stomach
- seizures or fits
- deafness

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

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

After using EDECIN

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store EDECIN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

EDECIN is a white capsule-shaped tablet, scored and embossed VRX 205 on one side, other side embossed EDECIN.

A bottle contains 100 tablets.

Ingredients

EDECIN contains 25 mg of ethacrynic acid per tablet as the active ingredient.

Inactive ingredients:

- lactose
- magnesium stearate
- silica colloidal anhydrous
- maize starch
- purified talc

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

EDECIN is supplied in Australia by:

A. Menarini Australia Pty. Ltd.

A.B.N. 62 116 935 758

Level 8/67 Albert Avenue

CHATSWOOD, NSW 2067

Phone: 1-800-642-646

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