

Dihydergot[®]

dihydroergotamine mesylate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dihydergot.

It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Dihydergot against the benefits it can 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 Dihydergot is used for

- Dihydergot is used to treat attacks of migraine, “cluster” headaches and other similar types of headache.

These headaches are thought to be caused by temporary changes in the size of small blood vessels in the brain. These blood vessels swell, causing the pain and visual disturbances that often happen during an attack. Dihydergot stops the attack by causing the blood vessels to constrict (shrink) back to normal size.

Dihydergot is only used to treat migraine attacks. It is not used to prevent attacks from happening.

There are some types of headaches which must not be treated with Dihydergot. Your doctor will determine the best treatment for your headache.

- Dihydergot is also used in adults to prevent a large drop in blood pressure that happens in some people when they stand up from a sitting or lying position. This condition, called orthostatic hypotension, can cause severe, disabling attacks of dizziness and lightheadedness, sometimes with fainting.

Dihydergot contains the active ingredient dihydroergotamine. It belongs to a group of medicines known as the “ergot alkaloids.”

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.

Dihydergot is only available with a doctor’s prescription.

Before you have Dihydergot

When you must not have it

Do not have Dihydergot if you have ever had an allergic reaction to any of the following:

- dihydroergotamine, the active ingredient in Dihydergot
- any of the other ingredients of Dihydergot listed at the end of this leaflet
- any other ergot alkaloids (e.g. Cafergot[®], Deseril[®], Ergodryl[®], Ergometrine[®], Kripton[®], Parlodel[®], Syntometrine[®]).

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 have Dihydergot if you have any of the following health problems / medical conditions:

- problems with your heart, especially if you have angina that is not controlled or you have had a heart attack
- high blood pressure that is not controlled
- poor blood circulation or other blood vessel disorders (e.g. varicose veins, fluid buildup in legs or feet, or conditions that make your fingers and toes unusually sensitive to cold)
- severe liver disease
- a serious infection
- you are being treated for HIV/AIDS with a medicine called ritonavir, nelfinavir, indinavir or delvaridine
- you are being treated for an infection with a medicine called ketoconazole, itraconazole, erythromycin or clarithromycin

Do not have Dihydergot if you are pregnant or intend to become pregnant.

This medicine may affect your developing baby if you have it while you are pregnant.

Do not breast-feed if you are having Dihydergot.

The active ingredient in Dihydergot may pass into breast milk and may affect your baby.

Do not have Dihydergot 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 have it

Tell your doctor if you have liver problems or severe kidney problems.

Your doctor may want to take special precautions during your treatment.

Tell your doctor if you smoke.

Nicotine in cigarettes may increase the chance of you having an unwanted side effect called “ergotism” (excessive constriction of blood vessels). See Side Effects section for more information.

Tell your doctor if you are lactose intolerant.

Dihydergot 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.

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 store.**

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

- some medicines used to treat HIV/AIDS, including ritonavir, nelfinavir, indinavir, saquinavir
- some medicines for infections, including ketoconazole, itraconazole, fluconazole, clotrimazole, erythromycin, clarithromycin
- some medicines used to treat mental disorders, including nefazodone, fluoxetine, fluvoxamine
- other ergot alkaloids
- other medicines used to treat migraine such as sumatriptan, naratriptan and zolmitriptan
- glyceryl trinitrate, a medicine for your heart
- nicotine in medicines used to help you quit smoking, such as nicotine patches or chewing gum
- beta-blocker medicines such as propranolol, which are used to prevent migraine and also to treat heart problems and high blood pressure
- any other medicine that can cause blood vessels to contract (shrink).

You may need to take different amounts of your medicines or to take different medicines while you are

having Dihydergot. 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 having this medicine.

How Dihydergot is given

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

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.***How it is given***

Dihydergot is available as an injection and in tablet form. The injection is used to treat acute migraine and cluster headaches.

The injection is also used at the start of treatment of severe low blood pressure to see whether it will work. After that, tablets may be taken.

How much is given

Acute migraine attack: the usual dose is 1 mg by injection into the muscle or under the skin at the first sign of headache. If necessary, further doses can be given at 30 to 60 minute intervals up to a total of 3 mg. The total dose given in a week should not be more than 6 mg.

Cluster headache: the usual dose is 0.5 mg by slow injection into a vein.

Migraine in children under 12 years of age: one-third to two-thirds of the adult dose according to age.

Severe disabling low blood pressure in adults: the first dose of Dihydergot is usually given by slow injection into a vein. After that, ½ to 1 tablet can be taken three times a day, with the dose increased at weekly intervals, if

necessary. Doses of up to 40 to 60 mg a day may be needed for some people. When treatment is needed for a prolonged period, it may be possible to reduce the daily dose.

Do not use sumatriptan, naratriptan or zolmitriptan or any medicine containing ergot alkaloids (e.g. Cafergot® or Ergodryl®) at the same time as you have Dihydergot.

You must wait at least 24 hours before you use any other medicine containing ergot alkaloids, sumatriptan, naratriptan or zolmitriptan.

Do not have more than the maximum recommended daily and weekly doses of Dihydergot. Do not continue treatment for longer than your doctor recommends.

You may have an increased risk of serious side effects such as “ergotism” or retroperitoneal or pleuropulmonary fibrosis (see Side Effects section for more information).

If you forget to take the tablets

If it is more than 4 hours until your next dose is due, take the missed dose as soon as you remember. Then take your next dose at the usual time and continue on with your normal schedule.

If your next dose is due within 4 hours, skip the missed dose. Then take your next dose at the usual time.

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

If you have too much (Overdose)

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

Some of the symptoms of an overdose may include numbness, tingling or pain in the fingers and toes, nausea (feeling sick), vomiting, headache, fast heart beat, spinning sensation (vertigo), muscle twitching and seizures (fits).

While you are having Dihyergot

Things you must do

If you become pregnant while having Dihyergot, tell your doctor.

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

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

Tell any other doctor, dentist or pharmacist who treats you that you are having Dihyergot.

Things you must not do

Do not use Dihyergot to prevent a migraine attack from happening. This medicine should only be used to treat a migraine once it has started.

Avoid drinking grapefruit juice while you are having Dihyergot. Grapefruit juice may interfere with the action of Dihyergot in your body.

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.

This medicine is not appropriate for common 'tension' headaches.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Dihyergot affects you. Children should avoid doing things like riding bicycles or climbing trees.

This medicine may cause dizziness or vertigo (spinning sensation) in some people. Make sure you know how it affects you before you drive a car, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Dihyergot, even if you do not think it is connected with the medicine.

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

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 immediately if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; wheezing or troubled breathing
- signs of "ergotism" (excessive constriction of blood vessels) such as numbness, coldness, tingling or a pale or bluish colour in the fingers or toes, pain or spasms in muscles, weakness in the lower legs, chest pain
- pain in the lower back or side, associated with difficulty in passing urine or pain on

urinating, which may be a sign of retroperitoneal fibrosis, a thickening of the abdominal lining that can cause obstruction of the urinary tract

- shortness of breath, dry cough, pain in the chest or rib area, which may be a sign of pleuropulmonary fibrosis, a scarring and thickening of lung tissue
- seizures (fits)

The above are serious side effects that need medical attention.

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

- nausea (feeling sick) or vomiting
- diarrhoea
- headache
- dizziness or spinning sensation (vertigo)
- fast, slow or irregular heart beat
- shaking or tremor
- feeling anxious or restless
- dry mouth
- flushing of the skin

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 having Dihyergot

Storage

- Keep your medicine in the original container until it is time to have it.
- Store it away from light in a cool, dry place.
- Do not store Dihyergot 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 having Dihydergot or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Australian Registration Number.
Ampoules AUST R 13349
Tablets AUST R 13352

Product description

What it looks like

Dihydergot ampoules contain a clear colourless liquid in a 1 mL glass ampoule; packs of 5.

Dihydergot tablets are whitish round tablets with a break line and ZI on one side, SANDOZ on the other side; packs of 100.

Ingredients

Dihydergot ampoules contain 1 mg dihydroergotamine (as the mesylate salt) in 1 mL of liquid. The ampoule also contains ethanol, glycerol and water for injections.

Dihydergot tablets contain 2.5 mg dihydroergotamine mesylate. They also contain the following inactive ingredients:

- tartaric acid
- gelatin
- magnesium stearate
- stearic acid
- purified talc
- maize starch
- lactose

Sponsor

Dihydergot is supplied in Australia by:
NOVARTIS Pharmaceuticals
Australia Pty Limited
ACN 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1 800 671 203

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