

SCHEDULING STATUS: S2

EFFORTIL® 10 mg/1 ml Injection

Etilefrine hydrochloride

Read all of this leaflet carefully before you are given EFFORTIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What EFFORTIL is and what it is used for
2. What you need to know before you receive EFFORTIL
3. How EFFORTIL will be given
4. Possible side effects
5. How to store EFFORTIL
6. Contents of the pack and other information

1. What EFFORTIL is and what it is used for

What EFFORTIL is

EFFORTIL is a direct-acting sympathomimetic with prominent stimulating effect on β_1 -adrenoceptors and a mild stimulating effect on α -adrenoceptors and β_2 -adrenoceptors.

What EFFORTIL is used for

EFFORTIL is a blood pressure-enhancing medicine. EFFORTIL is used to treat blood pressure that is too low (hypotension).

2. What you need to know before you are given EFFORTIL

EFFORTIL should not be given to you:

- If you are hypersensitive (allergic) to etilefrine hydrochloride or any of the other ingredients of EFFORTIL (listed in section 6).
- If you have an uncontrolled overactive thyroid (thyrotoxicosis)
- If you have an adrenal gland tumour (phaeochromocytoma)
- If you have glaucoma (an eye problem with increased pressure in the eye)
- If you have some disorder of the prostate such as an enlarged prostate (prostatic hypertrophy) or a growth (prostatic adenoma) with difficulty passing urine
- If you have hypertension (high blood pressure)
- If you have coronary heart disease (narrowing of the blood vessels that supply the heart)
- If you have a disease of the heart muscle which is accompanied by excessive and constricting growth of the heart muscle called hypertrophic obstructive cardiomyopathy
- If you have circulatory regulation disorders associated with low blood pressure that becomes high blood pressure upon standing (hypotensive dysregulation)
- If you are in the first 3 months of pregnancy
- If you are breastfeeding
- If your heart does not pump enough blood through the body (decompensated heart failure)
- If you have constriction (stenosis) of the heart valves or large arteries

Warnings and precautions

Special care should be taken with EFFORTIL

Tell your doctor, pharmacist or healthcare provider before being given EFFORTIL:

- If you have constriction (stenosis) of the heart valves or large arteries
- If you have heart rhythm disorders, tachycardia
- If you have serious diseases affecting the heart and blood vessels
- If you have diabetes

- If you have an overactive thyroid gland (hyperthyroidism)

EFFORTIL can result in positive athlete doping tests.

Other medicines and EFFORTIL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

EFFORTIL can interfere with some other medicines, in particular:

- Guanethidine – to treat high blood pressure
- Mineralocorticoids – medicines used to regulate the balance of salts and water in the body
- Reserpine – to treat high blood pressure
- Thyroid hormones
- Sympathomimetics – medicines that mimic the action of the sympathetic nervous system such as tricyclic antidepressants and monoamine oxidase (MAO) inhibitors (to treat depression) and antihistamines used for hay fever and other allergies
- Some inhalation anaesthetics (halogenated aliphatic hydrocarbons) and cardiac glycosides (medicines used to increase the contraction of the heart muscle) in higher doses
- Dihydroergotamine (used to treat migraine)
- Atropine (a medicine in some eye drops or sometimes used in surgery as a muscle relaxant)
- Adrenergic blockers (α - and β -blockers) to lower blood pressure
- Antidiabetic medication

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

EFFORTIL must not be used during the first trimester (first three months) of pregnancy. Safety during the second and third trimesters has not been established. EFFORTIL may cause a reduced blood flow to the placenta and relaxation of the womb. EFFORTIL must not be used while breastfeeding because of the possibility that etilefrine passes into the breast milk.

It is not known if there are any effects on fertility in humans.

Driving and using machines

Dizziness (and tremor or shaking) may occur with EFFORTIL. If affected, you should not drive or use machinery.

3. How EFFORTIL will be given

Your doctor will decide on the appropriate dosage for you.

EFFORTIL will be administered by intravenous injection or drip infusion after mixing in specified drip solutions, or by injection under the skin or into the muscle.

You will not be expected to give yourself EFFORTIL. It will be given to you by a person who is qualified to do so.

If you receive more EFFORTIL than you should

Since a healthcare provider will administer EFFORTIL, he / she will control the dosage. However, in the event of overdosage, your doctor will take appropriate actions.

If you forget to use EFFORTIL

Since a healthcare provider will administer EFFORTIL, it is unlikely that the dose will be missed.

4. Possible side-effects

EFFORTIL can have side effects.

Not all side effects reported for EFFORTIL are included in this leaflet. Should your general health worsen while being given EFFORTIL, please consult your doctor for advice.

If any of the following happens, stop receiving EFFORTIL and tell your doctor immediately if you are in hospital or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EFFORTIL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you are in hospital, or go to the casualty department at your nearest hospital if you are no longer in hospital, and you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats (for example, if you notice it beating faster),

These are serious side effects. You may need urgent medical attention.

Consult your doctor if you notice any of the following:

Frequent side effects

- Headache

Less frequent side effects

- Feeling anxious (anxiety)
- Difficulty sleeping (insomnia)
- Restlessness (akathisia)
- Dizziness
- Tremor (shaking)
- Nausea (feeling sick)
- Sweating (hyperhidrosis)

If any of these side effects become troublesome, please consult your doctor, pharmacist or other healthcare provider.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Pharmaco: 011 784 0077 (Tel), or
- SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of EFFORTIL.

5. How to store EFFORTIL

Store all medicines out of reach of children.

Store at or below 30 °C in a dry place and protect from light.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EFFORTIL contains

The active substance is etilefrine hydrochloride.

Each ampoule contains 10 mg of etilefrine hydrochloride.

The other ingredient is water for injection.

What EFFORTIL looks like and contents of the pack

A clear colourless solution in 1 ml amber glass ampoules.

Boxes containing 5 ampoules.

Holder of Certificate of Registration

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton 2196,

South Africa.

Ethical assistance Line: +27 (0) 11 784 00 77

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