

PACKAGE LEAFLET: INFORMATION FOR THE USER

DIETHYLSTILBESTROL 1 MG FILM-COATED TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Diethylstilbestrol is and what it is used for
2. What you need to know before you take Diethylstilbestrol
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1. What Diethylstilbestrol is and what it is used for

Diethylstilbestrol 1 mg film-coated tablets, referred to as Diethylstilbestrol in this leaflet, is a synthetic non-steroidal oestrogen hormone used specifically for men with prostate cancer who have not responded to other drug or surgery forms of castration and for whom alternative treatments are not suitable.

2. What you need to know before you take Diethylstilbestrol

Do NOT take Diethylstilbestrol if you:

- are allergic to diethylstilbestrol or any of the other ingredients of this medicine (listed in section 6)
- are currently suffering from liver disease
- have moderate or severe high blood pressure
- have any heart problems
- have a history of blood clots
- have any disorder of the blood vessels in the brain
- have hyperlipoproteinaemia (an excess of lipoproteins in the blood)
- untreated polycythaemia (increased production of red blood cells), or sickle cell anaemia (altered shape of red blood cells) which causes anaemia
- have porphyria (a deficiency of specific enzymes within the body, causing an increase of substances called porphyrins).

Warnings and precautions

Talk to your doctor before taking this medicine if you:

- suffer from kidney problems
- have ever had any liver problems or have suffered from jaundice (yellowing of the skin or whites of the eyes)
- suffer from mild high blood pressure
- have diabetes

- suffer from epilepsy
- suffer from migraine
- suffer from depression
- wear contact lenses
- suffer from gallstones
- suffer from thyroid problems.

If you have a thyroid function test while you are taking this medicine, make sure you have told the doctor that you are taking Diethylstilbestrol, as this may affect the results.

Children

Diethylstilbestrol should NOT be used in children (see section 3).

Other medicines and Diethylstilbestrol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, talk to your doctor if you are taking any of the following:

- diuretics or water tablets
- medicines used for high blood pressure.

Pregnancy

Diethylstilbestrol should NOT be used by women of childbearing age.

Driving and using machines

Diethylstilbestrol is not known to affect your ability to drive or operate machinery.

Diethylstilbestrol contains lactose and E110 (sunset yellow)

- Patients who are intolerant to **lactose** should note that Diethylstilbestrol tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Your medicine contains the colouring agent (sunset yellow) which may cause allergic reactions.

3. How to take Diethylstilbestrol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water.

In some patients, the doctor may consider prescribing a blood thinning agent such as low dose aspirin to prevent clots forming. Before taking diethylstilbestrol, your doctor may offer you breast bud radiation to minimise some of the side effects associated with diethylstilbestrol

How much to take

The recommended dose is:

Adults, including the elderly

Prostate cancer - One to three 1 mg tablets per day.

Use in children

Diethylstilbestrol should NOT be used in children.

If you take more Diethylstilbestrol than you should

If you (or someone else) take too many tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor **immediately**. The most common symptoms of overdose are feeling or being sick (nausea or vomiting). Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Diethylstilbestrol

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. **DO NOT** take a double dose to make up for a forgotten dose.

If you stop taking Diethylstilbestrol

You should continue to take these tablets for as long as your doctor tells you to. **DO NOT** stop taking your medicine without talking to your doctor first even if you feel better.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Diethylstilbestrol can cause side effects, although not everybody gets them.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- blood clots (causing redness, swelling and pain in the affected area).

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

Tell your doctor immediately if the following happens:

- gallstones and associated jaundice (causing yellowing of the skin or whites of the eyes).

The following side effects have been reported:

- aches and pains
- darkening/discoloration of the skin
- fluid retention
- headache
- increased incidence of migraine
- high blood pressure
- feeling sick (nausea) and being sick (vomiting)
- skin rashes
- weight gain
- sodium retention causing symptoms such as increased thirst, dry mouth, loss of skin elasticity, irritability, muscle twitching
- above normal glucose levels in the blood, which may increase the risk of diabetes
- fluctuating moods (both elation and depression)
- tender inflamed skin marked by red nodules
- discomfort of the eyes in patients wearing contact lenses
- breast discomfort, breast tenderness, breast enlargement and secretion of milk-like fluid from the breasts in both men and women
- in women, withdrawal bleeding, excessive production of cervical mucous, thickening of the lining of the uterus and uterine tumours. With prolonged use there may be an increased risk of malignant tumours in the lining of the uterus.

- in women, high calcium levels in the blood causing nausea, vomiting, loss of appetite, weakness, headache, bone pain, sleepiness or apathy
- in men, increased size of male breasts, reduction in size of testes, inability to get or maintain an erection.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5. How to store Diethylstilbestrol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Diethylstilbestrol tablet contains

- The active substance is diethylstilbestrol. Each 1 mg tablet contains 1mg of diethylstilbestrol.
- The other ingredients are lactose monohydrate, magnesium stearate (E572), maize starch, ethanol, opadry II pink 85F24252 consists of: polyvinyl alcohol, titanium dioxide (E171) polyethylene glycol/macrogol, talc, erythrosine aluminium lake (E127), sunset yellow FCF aluminium lake (E110) and indigo carmine aluminium lake (E132).

What Diethylstilbestrol tablets looks like and contents of the pack

Diethylstilbestrol 1 mg film-coated tablets are pink, biconvex, film-coated tablets, plain on one side and inscribed D1 on the reverse for oral administration. The tablets are available in blister packs of 10, 28, 30, 56, 60 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd.
5 Marryat Close, Hounslow West
Middlesex, TW4 5DQ, United Kingdom

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