

DIETHYLSTILBESTROL 1 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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. 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 is a synthetic non-steroidal oestrogen hormone.

Diethylstilbestrol is used to treat:

- prostate cancer in men
- breast cancer in post-menopausal women.

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

Female patients only:

- if you have not yet reached your menopause
- if you have an oestrogen dependant cancer, especially of the genital tract
- if you have endometrial hyperplasia (thickening of the womb lining)
- if you have uterine fibroids (fibrotic lesions in the uterus)
- if you have vaginal bleeding where the cause has not been diagnosed by your doctor
- if you have a history of herpes gestationis, a rare skin disorder of pregnant women.

Warnings and precautions

Talk to your doctor before taking Diethylstilbestrol:

- if you suffer from kidney problems
- if you have ever had any liver problems or have suffered from jaundice (yellowing of the skin or whites of the eyes)
- if you suffer from mild high blood pressure
- if you have diabetes
- if you suffer from epilepsy
- if you suffer from migraine
- if you suffer from depression
- if you wear contact lenses
- if you suffer from gallstones
- if you 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 it may affect the results.

Other medicines and Diethylstilbestrol

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

Talk to your doctor if you are taking any of the following:

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

Pregnancy and breast-feeding

- 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 sunset yellow

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Your medicine contains the colouring agent E110 (sunset yellow) which may cause allergic reactions.

3 How to take Diethylstilbestrol

Always take this medicine exactly as your doctor 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.

The recommended dose is:

Adults, including the elderly

- **Prostate cancer**
One to three 1 mg tablets per day.
- **Post-menopausal breast cancer**
10 - 20 mg per day.

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.
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 on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine 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
- breast discomfort, breast tenderness
- darkening 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
- 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 or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

These tablets should be stored in a dry place below 25°C, protected from light.

Do not use this medicine after the expiry date which is stated on the outer packaging. 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 tablets contain

- The active substance is 1 mg of diethylstilbestrol.
- The other ingredients are lactose, magnesium stearate (E572), maize starch, talc, polyvinyl alcohol, macrogol and the colouring agents E110 (sunset yellow), E127 (erythrosine), E132 (indigo carmine) and E171 (titanium dioxide).

What Diethylstilbestrol tablets look like and contents of the pack

- Diethylstilbestrol 1 mg tablets are pink biconvex, film-coated tablets, plain on one side and inscribed APS 1313 on the reverse.
- The product is available in packs of 10, 28, 30, 56, 60 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

TEVA UK Limited, Eastbourne, BN22 9AG.

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