Take special care with Diethylstilbestrol
Tell your doctor before you start to take this medicine:
• suffer from kidney problems
• have ever had any liver problems or have suffered from jaundice (yellowing of the skin or whites of the eye)
• suffer from mild high blood pressure
• have diabetes
• suffer from epilepsy
• have been told you have an enlarged prostate gland
• 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 it may affect the results.

Taking other medicines
Tell your doctor if you are taking any of the following:
• diuretics or water tablets
• medicines used for high blood pressure.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important information about some of the ingredients of this medicine
• Patients who are intolerant to lactose should note that Diethylstilbestrol tablets contain a source of lactose.
• Your doctor or pharmacist has not told you to take this medicine.
• Your medicine contains the colouring agent E10 (sunset yellow) which may cause allergic reactions.

Pregnancy and breast-feeding
Tell your doctor or pharmacist if you are pregnant or planning to become pregnant. This medicine is not recommended for use in pregnancy.

Keep out of reach of children.

How to take Diethylstilbestrol

Do not take Diethylstilbestrol if you:
• are allergic (hypersensitive) to diethylstilbestrol or any of the other ingredients of this medicine
• are currently suffering from liver disease
• have moderate or severe high blood pressure
• have heart problems
• have a history of blood clots
• have an inherited disorder of the blood vessels in the brain
• have myasthenia gravis
• have porphyria (a deficiency of specific enzymes within the body, causing an increase of substances called porphyrins).

Female patients only:
• have not yet reached your menopause
• have an oestrogen dependent cancer, especially of the genital tract
• have endometrial hyperplasia (thickening of the womb lining)
• have uterine fibroids (fibrotic lesions in the womb lining)
• have vaginal bleeding where the cause has not been diagnosed by your doctor.
• do not have treatment for hyperthyroidism, a rare skin disorder of pregnant women.

Take care when you drive or operate machinery.

Diethylstilbestrol is a synthetic non-steroidal oestrogen hormone.

Diethylstilbestrol should not be used in women who:
• have a history of herpes gestationis, a rare condition marked by red nodules
• have uterine fibroids (fibrotic lesions in the womb lining)
• have an oestrogen dependant cancer, especially of the genital tract

Female patients only:
• have porphyria (a deficiency of specific enzymes in the body)
• have hyperlipoproteinaemia (an excess of fats in the blood)
• have carcinoid syndrome
• have an inherited disorder of the blood vessels in the brain
• are allergic (hypersensitive) to diethylstilbestrol or any of the other ingredients of this medicine

Diethylstilbestrol 1 mg AND 5 mg TABLETS
PACKAGE LEAFLET  INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

• 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 symptoms 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.

DO NOT take Diethylstilbestrol if you:
• breast cancer in post-menopausal women.

Diethylstilbestrol is used to treat:
• breast cancer
• prostate cancer
• endometrial hyperplasia

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

The usual dose is:
• Adults, including the elderly
• Post-menopausal breast cancer
• Post-menopausal breast cancer: Two to five 5 mg tablets 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

awaliensf any of the tablets contact your nearest hospital casualty department or your doctor immediately.

The most common symptoms of overdose are:
• fever
• confusion
• increased rate of breathing
• sweating
• vomiting

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 or pharmacist tells you. DO NOT stop taking your medicine without telling your doctor first even if you feel better.

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

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 or swallowing)
• 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:
• any of the following symptoms associated with jaundice (yellowing of the skin or whites of the eyes). The following side effects have been reported:
• achy and pains
• breast discomfort, breast tenderness
• darkening of the skin
• fluid retention
• headaches
• increased incidence of migraine
• high blood pressure
• feeling sick (nausea) and being sick (vomiting)
• skin rash
• 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
• flushing of both skin and face
• tender inflamed skin marked by red nodules
• depression of the eyes in patients wearing contact lenses
• enlargement and secretion of milk like fluid from the breasts in both men and women
• 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

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

HOW TO STORE DIETHYLSTILBESTROL

Keep out of the reach and sight of children.
These tablets should be stored in a dry place below 25°C, protected from light.

Do not use Diethylstilbestrol after the expiry date that is stated on the Outer Carton and blister packs. The expiry date refers to the last day of that month.

Diethylstilbestrol tablets contain:
• The active ingredient is either 1 mg or 5 mg of diethylstilbestrol.
• The other ingredients are, anhydrous lactose, magnesium stearate (E473), maize starch, talc, povidone, sodium lauryl sulphate and the colouring agent E10 (sunset yellow) (titanium dioxide).

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

What side effects may be expected:
• The active ingredient may cause:
• 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, joint pain, shakiness or apathy
• in men, increased size of male breasts, reduction in size of testes, inability to get or maintain an erection.

FURTHER INFORMATION

What Diethylstilbestrol tablets contain:
• The active ingredient is diethylstilbestrol.

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 1013 on the reverse.
• Diethylstilbestrol 5 mg tablets are pink biconvex, film-coated tablets, plain on one side and inscribed APS 1014 on the reverse.
• The product is available in packs of 10, 20, 30, 50, 60 and 100 tablets.

All pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer
Marketing Authorization holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN23 6AA.

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