

Package leaflet: Information for the patient

Dexametason Abcur 1 mg tablets

Dexametason Abcur 4 mg tablets

dexamethasone

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dexametason Abcur is and what it is used for
2. What you need to know before you take Dexametason Abcur
3. How to take Dexametason Abcur
4. Possible side effects
5. How to store Dexametason Abcur
6. Contents of the pack and other information

1. What Dexametason Abcur is and what it is used for

The active substance in Dexametason Abcur is dexamethasone. Dexamethasone belongs to a group of medicines called corticosteroids.

Dexametason Abcur is mainly used for intensive care for treatment of inflammations and certain allergic reactions. Dexamethasone is also used in the treatment of for example inflammations in connection to cancer diseases and to prevent vomiting at treatment with cytostatic agents. Dexamethasone is used at brain oedema and swelling of the brain due to brain tumour.

Dexametason Abcur may also be used for controlling the function of the adrenal cortex and the pituitary.

Dexametason Abcur is used as a treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) with difficulty breathing and need of oxygen therapy.

2. What you need to know before you take Dexametason Abcur

Do not take Dexametason Abcur

- if you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6).
- if you have a fungal infection that affects the whole body

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Dexametason Abcur, if you have:

- diabetes,
- tuberculosis,
- osteoporosis,

- psychiatric disorders,
- gastric- and duodenal ulcer
- hypertension,
- hypokalemia,
- migraine,
- heart failure,
- problems with the muscles in your heart after a recent heart attack,
- renal failure,
- eye diseases,
- an infection.
- If you will be vaccinated, you should inform the person who shall carry out the vaccination that you are using Dexametason Abcur.
- Contact your doctor if you have fever or feel stressed since these strains may require a change of the dose.
- Dexametason Abcur should not be given in conjunction with a head injury or stroke.
- Discontinuation of the dose should be done gradually.

You should tell your doctor if you have any of the following:

Symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you suffer from haematological malignancy.

Contact your doctor if you experience blurred vision or other visual disturbances.

Dexamethasone should not be used routinely in preterm neonates with respiratory problems.

Treatment of Covid-19

You should not stop taking any other steroid medications unless your doctor has instructed you to do.

General precautions need to be taken in line with current recommendations regarding steroid use in specific diseases, masking infection, concomitant medicines etc.

Children and adolescents

Dexametason Abcur may affect the growth of children.

Other medicines and Dexametason Abcur

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment may be affected if other medicinal products are taken concomitant with Dexametason Abcur. Your physician should be informed of such concomitant treatment.

Concomitant treatment with medicinal products for epilepsy (phenobarbital, phenytoin, carbamazepine, primidone), tuberculosis (rifampicin) and infections (itraconazole, cobicistat) may require dose adjustment.

Ask your doctor for advice before using products containing acetylsalicylic acid.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There is a risk that the fetus will be affected. This medicine should only be used during pregnancy if clearly necessary.

Breast-feeding

There is a risk that the breastfed baby will be affected. This medicine should only be used during breast-feeding if clearly necessary.

Fertility

If you are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Dexametason Abcur is not likely to affect you being able to drive or use any tools or machines.

Dexametason Abcur contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dexametason Abcur

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 dose is decided by your doctor who adjusts it individually for you. A usual dose for anti-inflammatory effect is 1-4 mg daily during the first week and thereafter 1-2 mg daily. *It is important that you follow the advice from the doctor and do not change the dose or terminate the treatment.*

For the treatment of Covid-19

Adult patients are recommended to take 6 mg once a day for up to 10 days.

Paediatric patients (adolescents of 12 years of age or older) are recommended to take 6 mg once a day for up to 10 days.

Contact your doctor or pharmacist if you experience that the effect of Dexametason Abcur is too strong or too weak.

The tablet can be divided into equal doses.

If you take more Dexametason Abcur than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Dexametason Abcur

Do not take a double dose to make up for a forgotten dose.

If you stop taking Dexametason Abcur

You should not stop taking steroid medications unless your doctor has instructed you to do.

If your treatment is to be stopped follow your doctor's advice. He/she may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether. The symptoms that have been reported when treatment has been stopped too quickly include low blood pressure and sometimes, relapse of the disease for which the medicine was given.

Sudden withdrawal of steroid medications may cause severe weakness, confusion, pain in your lower back or legs, severe abdominal pain, vomiting and diarrhea, leading to dehydration and reduced consciousness or delirium.

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

4. Possible side effects

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

When you take cortisone products in doses corresponding to the body's own production you don't normally get any side effects. If you need higher doses for a longer period side effects can sometimes not be avoided.

Common (may affect up to 1 in 10 people):

- Impaired resistance towards infections.
- Swelling of the face and skin redness in the face (Cushings syndrome).
- Growth retardation in children.
- Acne and growth of extra body hair in women.
- Muscle weakness.
- Thinning of the bones as a consequence of decalcification of the bone (osteoporosis).
- Decreased ability to take care of sugar which may worsen your diabetes and unknown diabetes becoming evident.
- Diabetes
- Low levels of nitrogen in the blood

Uncommon (may affect up to 1 in 100 people):

- Hypersensitivity reactions such as oedema, rash and eczema.
- Suppression of skin tests.
- Swelling in the body as a result of problems with salts in your blood such as too much sodium or low potassium or calcium.
- Increased appetite and weight increase.
- High blood pressure, blood clots and heart failure.
- Gastrointestinal disorders such as nausea and gastric ulcer.
- Thin and fragile skin (bruises easily), impaired wound healing
- Changed mood and sleeping disturbance, feeling of happiness, feeling low (depression), severe mental disorder (psychosis)
- Eye effects such as increase pressure in the eyes, glaucoma, pop-eyedness and cataracts.

Rare (may affect up to 1 in 1,000 people)

- Rupture of tendon
- Increased pressure inside the head.
- Decomposition of the tissue

Not known (frequency cannot be estimated from the available data) :

- Inflammation of the pancreas
- Irregular or missing periods
- Cramps
- Headache, dizziness, feeling general unwell.
- Bone fractures
- Muscle disease in arms and legs
- Blocking of blood vessels
- Swelling in the body as a result of fluid retention.
- Low levels of potassium in the blood.
- Problems with the muscles in your heart after a recent heart attack
- Tiny round purple spots, rash and skin redness.
- Bruising
- Excessive sweating
- Gastric ulcers which may perforate and bleed, ulcers in the throat, swollen stomach.
- Visual disturbances, loss of vision
- Blurred vision
- Decrease in carbohydrate tolerance

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 national reporting system listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexametason Abcur

Do not store above 30°C. Store in the original package in order to protect from light.

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 after EXP. 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 Dexametason Abcur contains

- The active substance is dexamethasone.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

What Dexametasone Abcur looks like and contents of the pack

Dexametason Abcur 1 mg is a round, biplanar, white to off-white tablet with bevelled edges and single break mark; embossed with „D | 1“.

Dexametason Abcur 4 mg is a round, biplanar, white to off-white tablet with bevelled edges and single break mark; embossed with „D | 4“.

Dexametason Abcur is available in:

Perforated PVC/PVDC/Alu unit-dose blisters with 20x1, 28x1, 30x1, 50x1, 56x1, 60x1, 98x1 or 100x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Abcur AB
P.O. Box 1452
251 14 Helsingborg
Sweden

Manufacturer

Cyndea Pharma S.L.
Polígono Industrial Emiliano Revilla Sanz.
Avenida de Ágreda, 31
Ólvega 42110 (Soria)
Spain

Formula Pharmazeutische und chemische Entwicklungs GmbH
Goerzallee 305 b
14167 Berlin

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