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|---------------|---|---|---|---|
| Product:      | <b>Dexamethasone Activase<br/>0.5 mg and 2 mg Tablets</b> | Printing Colours:   | Non-Printing Colours:   |  |
| MA Holder:    | <b>Activase</b>   |  Black |  Profile | Final Preparation Date For Submission: <b>30/03/2022</b>                            |
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| Pack Size:    | <b>All Pack</b>   | Dimensions:   | <b>192 x 540 mm</b>   | Authority Approval Date: <b>03/06/2022</b>  |
| Livery:       | <b>Activase</b>   | AW Code:  | <b>A002-001-002/IE/O/PIL/A1</b>   | Latest Implementation Deadline: <b>03/12/2022</b>                                   |
| Manufacturer: | -   | Bar Code:   | -   | Print Proof Approval:<br><b>00/00/0000</b>  |
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**Prompt list for artwork checks**

- Are the dimensions correct?
- Are the font sizes correct?
- Are the livery and colours correct?
- Is the content (text) correct?
- Is the braille correct?
- Is the artwork code correct?

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

#### Effects when treatment with Dexamethasone is stopped:

After therapy with Dexamethasone for a longer period, the dose should be gradually decreased in order to prevent a relapse of your disease and to allow your adrenal gland to recover its normal function.

Do not let yourself run out of medicine, especially over the weekends or on holidays.

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.

On short-term treatment:

- gastrointestinal complaints, such as an upset stomach or inflammation of the pancreas, ulcer of the stomach, ulcer of the duodendum, or bleeding ulcer
- hypersensitivity reactions (allergic reactions) e.g. rash, itch and difficulty in breathing and angioedema (swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)

On long-term treatment:

- filling or rounding of the face, neck and body
- dehydration or weakness
- hormone deficiency
- irregular periods or complete absence of periods
- abnormal hair growth
- weight gain or weight loss
- increased or decreased appetite
- in diabetics: the need for more insulin or antidiabetic tablets
- recurring infections or mild infections getting worse e.g. chickenpox; being less protected after inoculation; having a decreased response to skin test; recurrence of dormant tuberculosis (TB)
- brittle bones (osteoporosis) or bone disease (osteonecrosis)
- muscle weakness
- fluid retention in the tissues, usually marked by swelling of ankles or feet
- sodium retention, usually marked by an increase in blood pressure
- calcium deficiency
- high blood pressure
- potassium loss
- changes of mood (nervousness, depression, euphoria, psychological dependence and schizophrenia)
- sleeplessness
- aggravation of epilepsy

- certain eye diseases (increased pressure in the eye, glaucoma, papilloedema (optic nerve swelling), cataracts (clouding of vision), thinning of the cornea or outer wall (sclera), worsening of a viral or fungal eye disease, visual disturbances or loss of vision
- abdominal or stomach pain
- nausea and vomiting
- candidiasis (thrush)
- slower healing of wounds
- easy bruising; skin problems
- (spinal) fracture, tendon rupture
- telangiectasia (spider veins)
- in children: delayed or stunted growth and increased intracranial pressure (pseudo tumour cerebri)
- an increase in the amount of white blood cells in your blood
- a blood clot in your vessels
- In elderly: symptoms of diabetes (unusual thirst, frequent urination); loss of bone tissue with symptoms such as low back pain, loss of stature and fractures.
- Blurred vision

#### 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

HPRA Pharmacovigilance  
Earlsfort Terrace, IRL - Dublin 2,  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: www.hpra.ie  
e-mail: medsafety@hpra.ie

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

## 5. HOW TO STORE DEXAMETHASONE TABLETS

**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 blister, carton/container/label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container to protect from light and moisture.

Do not throw away any medicine 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 Dexamethasone Tablets contain

- The active substance in Dexamethasone 0.5 mg Tablets is dexamethasone (500 micrograms).
- The active substance in Dexamethasone 2 mg Tablets is dexamethasone (2000 micrograms).
- The other ingredients are: lactose monohydrate, magnesium stearate and maize starch (See end of Section 2 for further information on lactose).

#### What Dexamethasone Tablets look like and contents of the pack

Dexamethasone 0.5 mg Tablets are white, round, flat bevelled tablets of about 6.0 mm in diameter and 2.5-2.8 mm, thickness, debossed 'D' on top and '0.5' underneath on one side and plain on the other side.

Dexamethasone 2 mg Tablets are white, round, flat bevelled tablets of about 6.0 mm in diameter and 2.5-2.8 mm, thickness, debossed 'D' on top and '2' underneath on one side and plain on the other side.

#### Pack sizes

Dexamethasone 0.5 mg and 2 mg tablets are available in blister packs (opaque PVC-aluminium)  
10, 14, 20, 28, 30, 50, 56, 60, 90 and 100 tablets in blister pack

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Activase Pharmaceuticals Limited  
11 Boumpoulinas Street  
Nicosia 1060 Cyprus

#### Manufacturer

Elara Pharmaservice Europe Limited  
239 Blanchardstown Corporate Park  
Ballycoolin, D15 KV21, Dublin, Ireland

**This leaflet was last revised in 03/2022**

A002-001-002/IE/O/PIL/A1

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

# Dexamethasone Activase 0.5 mg Tablets Dexamethasone Activase 2 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 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 Dexamethasone Tablets is and what it is used for
2. What you need to know before you take Dexamethasone Tablets
3. How to take Dexamethasone Tablets
4. Possible side effects
5. How to store Dexamethasone Tablets
6. Contents of the pack and other information

## 1. WHAT DEXAMETHASONE TABLETS IS AND WHAT IT IS USED FOR

The name of your medicine is Dexamethasone. This belongs to a group of medicines called corticosteroids.

Corticosteroids are hormones that are found naturally in your body that help to keep you healthy and well. Taking extra corticosteroids, such as Dexamethasone, is used to treat various illnesses involving inflammation in the body.

Dexamethasone lowers inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Dexamethasone can be used to:

- Reduce inflammation
- Treat a number of different diseases of the immune system including:
  - Rheumatism (pain, stiffness or limitation of motion in the joints, muscles and tendons)
  - Inflammations including inflammation of the joints and tissue around the joint (rheumatoid arthritis), inflammation of the skin (such as contact dermatitis), the eye, blood vessels and other parts of the body
- Allergic conditions which cause joint pain, skin rashes and fever

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT  
Dexamethasone Activase 0.5 mg Tablets  
Dexamethasone Activase 2 mg Tablets

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Dexamethasone Activase 2 mg Tablets

- Hypersensitivity reactions (allergic reactions) to other drugs or insect stings
- Anaphylactic shock (severe sudden allergic reaction)
- Asthma
- Potential rejection of an organ or tissue transplant
- Disorders of the adrenal gland
- Swelling of the brain and part of the treatment for some types of cancer
- Lupus erythematosus

You must talk to a doctor if you do not feel better or if you feel worse

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEXAMETHASONE TABLETS

### Do not take Dexamethasone Tablets:

- If you are suffering from a stomach or intestinal ulcer
- If you have a general infection (caused by a virus or a fungus)
- If you are allergic to dexamethasone or any of the other ingredients in this medicine (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath.
- If you have a parasitic infection
- If you have recently had a vaccination with a live vaccine (especially chickenpox)

Do not take this medicine if any of the above apply to you

### Warnings and precautions

Treatment with this medicine may cause pheochromocytoma crisis, which can be fatal.

Pheochromocytoma is a rare tumor of the adrenal glands. Crisis can occur with the following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience any of these signs.

Talk to a doctor before taking dexamethasone

- **If you have ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like dexamethasone.
- **If any of your close family** has had these illnesses.
- If you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

### Mental problems while taking Dexamethasone

Mental health problems can happen while taking steroids like Dexamethasone tablets (see also section 4).

- These illnesses can be serious.
- Usually, they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about

suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Tell your doctor if you have 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.

If you have been using Dexamethasone for a longer period, the therapy may never be stopped abruptly. If during prolonged therapy any intercurrent illness, trauma or surgical procedure occurs, your doctor may decide to temporarily increase the dosage. Dexamethasone may mask symptoms of an infection and new infections may develop during therapy. Vaccines should, in certain circumstances, not be given to you during therapy. Your doctor will decide for you whether or not this is relevant to you. Exposure to chickenpox, shingles or measles should, if you have not had these diseases before, be avoided during therapy. Please contact your doctor if, for some reason, you have been exposed to chickenpox or measles during therapy. The common side effects of Dexamethasone may be associated with more serious consequences in old age, especially osteoporosis, high blood pressure, low potassium levels in the blood, diabetes, susceptibility to infection and thinning of the skin. Extra supervision by your doctor is necessary.

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

Before Dexamethasone is given to you, it is also important to tell your doctor if you have or ever had:

- Brittle bones (osteoporosis);
- High blood pressure or heart disease;
- Mental illness;
- Diabetes (or a family history of diabetes);
- Tuberculosis;
- Certain visual disturbances (glaucoma);
- Disease of the muscles (glucocorticoid-induced myopathy);
- Liver disease (liver failure);
- Kidney disease (renal insufficiency);
- Epilepsy;
- Peptic ulcer.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Dexamethasone

### Children

Extra supervision by your doctor is necessary when Dexamethasone is used to treat children since glucocorticoids may affect growth.

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

### Other medicines and Dexamethasone Tablets

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

Some medicines may be affected by dexamethasone or they may affect how well dexamethasone will work. Tell your doctor or pharmacist if you are taking:

- Medicines used to treat epilepsy such as phenobarbitone, phenytoin, primidone and carbamazepine
- Medicines used to treat tuberculosis such as rifampin and rifabutin
- Medicines used to treat certain cancers such as aminoglutethimide
- Antidiabetic medicines used to control blood sugar levels, including insulin
- Medicines used to control blood pressure and diuretics (to stimulate urination)
- Medicines used to treat myasthenia gravis such as anticholinesterases
- Use of certain diuretics (potassium-depleting diuretics such as acetazolamide, loop diuretics, thiazide diuretics or carbenoxolone) during therapy with Dexamethasone may result in hypokalaemia (a shortage of potassium).
- Certain anticoagulants used to prevent blood clots such as coumarines
- The clearance of salicylates (e.g. aspirin) is increased during treatment with Dexamethasone. Therefore, if you stop using Dexamethasone, the dosage of salicylates should be lowered to prevent blood levels becoming too high and causing unwanted effects.
- Combination of corticosteroids with medicines which can cause stomach ulcers (e.g., painkillers like aspirin, ibuprofen) increases the risk of stomach ulcers.
- Dexamethasone can diminish the effects of medicines which are broken down in the body by an enzyme in the liver (CYP 3A4), for example, HIV protease inhibitors (e.g., indinavir), and certain antibiotics (e.g. erythromycin).
- Some medicines may increase the effects of Dexamethasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

### 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 for advice before taking this medicine.

#### Pregnancy

Dexamethasone should not be used for a prolonged period during pregnancy. If you receive Dexamethasone often or over a long period of time during pregnancy there may be a risk that the baby's growth slows down.

#### Breast-feeding

It is not known whether or not Dexamethasone is excreted into breast milk. Breast-feeding during treatment with Dexamethasone is therefore discouraged.

### Driving and using machines

Glucocorticoids may cause mood changes or visual disturbances. If you notice this, caution should be exercised in driving and operating machinery.

### Dexamethasone Tablets contains lactose

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 DEXAMETHASONE TABLETS

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

### Taking this medicine

- Your doctor will tell you how many tablets to take. This will depend on your illness and how bad it is.
- Take this medicine by mouth.
- Swallow the tablets with some water. Take the tablets at about the same time each day, preferably in the morning.

### Usual dose for adults

- The usual dose is 0.5mg to 10mg each day

When you get better the dosage is gradually decreased, preferably to one morning dose on alternate days.

### If you take more Dexamethasone than you should

If you took more Dexamethasone than you should, talk to a doctor or pharmacist immediately.

### If you forget to take Dexamethasone

Find the type of dose you take in the chart below and follow the instructions.

| Your dose   | What to do   |
|---|--|
| One dose several times a day                        | Take the missed dose as soon as you remember, even if this means taking two doses at once  |
| One dose a day (preferably in the morning)          | If you remember on the same day, take the missed dose as soon as possible. If you do not remember until the next day, just skip the missed dose and take only the dose for that day. Do not take a double dose.                          |
| One dose every two days (preferably in the morning) | If you remember on the same morning, take the missed dose as soon as possible. If you remember later in the day, wait and take the dose the next morning. Then miss a day and start your regular pattern again in the following morning. |

### If you stop taking Dexamethasone

It can be dangerous to stop taking this medicine suddenly. If you need to stop this treatment, follow your doctor's advice. He or she may tell you to lower the amount of medicine you are taking gradually until you stop taking it altogether. If you stop taking this medicine too quickly, your condition may get worse.

You may also feel a 'withdrawal symptom'. These may include headache, problems with your vision (including pain or swelling in the eye), feeling or being sick, fever, pain in your muscles and joints, swelling in the inside of your nose, weight loss, itchy skin and conjunctivitis.

## Dexamethasone Activase 0.5 mg and 2 mg Tablets

| AW Code                  | Version | Date       | Req by | Change Reasons |
|--------------------------|---------|------------|--------|----------------|
| A002-001-002/IE/O/PIL/A1 | 0.1     | 30/03/2022 | PB     | New launch     |