

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

Information for the patient

[CV004 trade name][†]
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 questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [CV004 trade name] is and what it is used for
2. What you need to know before you take [CV004 trade name]
3. How to take [CV004 trade name]
4. Possible side effects
5. How to store [CV004 trade name]
6. Contents of the pack and other information

1. What [CV004 trade name] is and what it is used for

[CV004 trade name] is a medicine containing the active substance dexamethasone. Dexamethasone is a corticosteroid medicine (sometimes just called a steroid). Corticosteroids act to help control inflammation and overactivity of the immune system (the body's natural defences) associated with a number of serious diseases.

[CV004 trade name] is used when treatment with a corticosteroid medicine by mouth is not suitable and an injection or infusion (drip) is needed.

[CV004 trade name] may be used to treat conditions such as

- swelling (oedema) of the brain, like that due to a brain tumour, brain surgery or meningitis associated with tuberculosis or some other bacteria
- shock (steep fall in blood pressure) that does not respond to other treatments, where a corticosteroid is thought likely to be helpful
- preventing and treating nausea (feeling sick) or vomiting after surgery or cancer treatment
- some symptoms of terminal illness such as lack of appetite, difficulty breathing or swallowing, pain and pressure on the spinal cord from a tumour
- other serious illnesses associated with allergy, inflammation or autoimmunity (when the immune system mistakenly attacks the body's own tissues).

Dexamethasone may also be used as a treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older with body weight of at least 40 kg) with difficulty breathing and in need of oxygen therapy.

[CV004 trade name] can be injected directly into a joint or the area around a joint or tendon to treat inflammation, as long as it is not due to an infection, and can be injected into swellings and areas of inflammation caused by certain skin diseases.

[†]Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

2. What you need to know before you are given [CV004 trade name]

[CV004 trade name] must not be used

- If you are allergic to dexamethasone or any of the other ingredients of this medicine.
- If you have an infectious disease (including a fungal, viral or parasitic infection) that is not being treated with a medicine to control the infection.
- By injection into a joint that is unstable (weakened), or into a joint or inflamed skin area where there is infection

Warnings and precautions

Your health care provider may recommend a change in the dose of other steroid treatments you may be taking, if you are given [CV004 trade name]. You should not stop taking any other steroid medications unless your health care provider has instructed you to do so. Talk to your health care provider before you take [CV004 trade name].

Talk to your health care provider before you are given [CV004 trade name] if you have or have ever had:

- Osteoporosis (a disease that causes thinning and fragile bones)
- high blood pressure (hypertension), or congestive heart failure
- diabetes, or if anyone in your immediate family has diabetes
- glaucoma (an eye disease associated with high pressure in the eye)
- muscle weakness due to previous corticosteroid treatment
- myasthenia gravis (a disease causing muscle weakness)
- liver failure
- reduced kidney function
- epilepsy
- migraine
- Cushing's syndrome.

Your health care provider may need to take extra care and monitor you more closely.

Your health care provider will adjust your dose depending on your condition and how it responds to treatment. Your dose may need to be increased if you need surgery, have an accident, or become ill with another condition. If you have reduced thyroid function, or have cirrhosis (scarring) of your liver, you may need a lower dose.

Corticosteroids like [CV004 trade name] can affect mood and the way you think, including thoughts of suicide. If you

- have ever suffered from disorders of mood such as depression, mania or bipolar disorder, *or*
- have previously had disturbed thoughts or behaviour after treatment with a corticosteroid medicine (corticosteroid-induced psychosis)

talk to your health care provider before you are given this medicine.

You should also tell your health care provider if you have an ulcer of your stomach or upper bowel (peptic ulcer), ulcerative colitis or diverticulitis (disorders of the intestines), abscess or other infection of the intestines, or have recently had surgery on your gut. Corticosteroids can make these conditions worse, and sometimes lead to perforation of the walls of the gut.

Corticosteroid medicines can cause some infections that have been suppressed to return. Tell your health care provider if you have had tuberculosis or amoebiasis (a parasitic infection that causes diarrhoea) in the past. Because treatment with [CV004 trade name] can increase the risk of severe infection you must try to avoid exposure to people with infectious diseases such as chickenpox or measles.

When corticosteroid medicines are taken for more than a few days and in relatively high doses they can suppress the body's ability to make its own natural corticosteroids in the adrenal glands. Because the body depends on a certain level of these natural corticosteroids to be able to respond to stress and illness, if this happens it is important that your corticosteroid medicine is stopped slowly, to give the body's natural production time to recover. Your health care provider will monitor your body's response and if necessary will slowly reduce the dose of your medicine once you no longer need it.

Injection into joints can sometimes have effects elsewhere in the body because some of the medicine will pass into the bloodstream. Joint injections should not be given too often, as they can result in damage to the joint. Tell your health care provider if you get an increase in pain and swelling, stiffness, or a fever and general feeling of being unwell, after injection into a joint.

Children and adolescents

In children and young people, who have not finished growing, prolonged treatment with corticosteroids may cause a reduction in normal bone growth, particularly if high doses are used. In some cases, this can cause the patient's adult height to be reduced.

Elderly

If you are elderly, and particularly if you are a woman past the menopause, you may be at higher risk of osteoporosis with corticosteroid treatment. Older patients may also be at higher risk of high blood pressure.

Use in athletes

This medicine contains an ingredient that can produce positive results in doping tests.

Taking other medicines

Tell your health care provider if you are taking or have recently taken or are planning to take any other medicines. In particular:

- you must not be given a live vaccine (a vaccine containing living organisms) such as some chickenpox (varicella) vaccines while being treated with [CV004 trade name]. **Tell your health care provider if you are planning to have a vaccination.**

It is also important to tell your health care provider if you are taking any of the following medicines. Special care or an adjustment of your dose may be needed:

- adrenaline (for allergic reactions and breathing problems)
- albendazole, a medicine for worm infections
- aminoglutethimide (a medicine for Cushing's syndrome and certain cancers)
- anticoagulants such as warfarin
- carbenoxolone (a medicine for stomach ulcer)
- chloroquine, hydroxychloroquine (medicines used for malaria and some rheumatic and immune system disorders)
- diabetes medicines, including insulin
- digoxin and cardiac glycosides (medicines that regulate the heart)
- diuretics (medicines to increase urine flow and lower blood pressure such as furosemide or bendroflumethiazide)
- ephedrine (a decongestant)
- erythromycin, isoniazid, rifampicin (antibiotics, including for tuberculosis)
- fluoroquinolone antibiotics such as ciprofloxacin
- some HIV medicines such as cobicistat, indinavir and ritonavir
- non-steroidal anti-inflammatory medicines (NSAIDs) such as indomethacin and ibuprofen
- oestrogens (female hormones, including in oral contraceptives and HRT)
- phenytoin, phenobarbital, carbamazepine (medicines used mainly for epilepsy)

Effect on laboratory results

This medicine can alter the values of some laboratory tests. If you are asked to undergo a laboratory test, tell your health care provider that you are using [CV004 trade name].

Pregnancy and breast-feeding

Pregnancy

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

[CV004 trade name] should not be taken if you are pregnant unless clearly indicated by your health care provider.

Breastfeeding

Corticosteroids may pass into breast milk, although no data are available for dexamethasone. If you are breastfeeding or planning to breastfeed, ask your health care provider for advice on the benefits of treatment versus any risks to you and your baby.

Driving and using machines

Do not drive or operate machinery if you get any side effects like blurred vision that might affect your ability to do so. However, treatment with this medicine is not normally expected to affect the ability to drive or use machinery.

[CV004 trade name] contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

3. How [CV004 trade name] is given

[CV004 trade name] will be given to you by your health care provider. The medicine can be given by injection or infusion (drip) into a vein, or by injection into a muscle. For some conditions it may be injected directly into the affected area such as a joint or swelling.

Your health care provider will work out the right dose for you, based on the severity of the illness and your general condition, and will decide the best way to give the medicine.

Your health care provider will also decide how long you should take [CV004 trade name] for. Check with your health care provider if you are not sure.

Injection into a vein or muscle

Usual doses into a vein or muscle are between 0.4 and 9 mg, but in severe cases much higher doses may be needed. Doses in children are usually based on their weight.

If you need repeated doses, the dose will be adjusted depending on how well the condition responds and any side effects you may get. If you need surgery or develop another illness the dose may be temporarily adjusted to compensate.

If you are only being given the medicine once a day, doses will be given in the morning if possible. This is to reduce any effect on the body's production of its own natural corticosteroids.

In most cases, treatment will not be needed for more than a week or two. You may be switched to tablets if longer treatment is needed.

Injection into a joint or affected area

Direct injections of [CV004 trade name] into a joint or affected area may only need to be given once, and if they need to be repeated this is likely to be after several days or weeks.

For the treatment of Covid-19

For adults and adolescents of 12 years of age or older the recommended dose of [CV004 trade name] is 6 mg once a day for up to 10 days.

If you are given too much or too little [CV004 trade name]

As this medicine is given to you by a health care provider, who will adjust the dose carefully to suit your needs, it is unlikely that you will be given too much or too little dexamethasone.

If you think that you have been given the wrong dose, or missed a dose, talk to your health care provider if you have any concerns.

Stopping [CV004 trade name]

Corticosteroid medicines such as [CV004 trade name] can stop the body from producing its own natural corticosteroids, which are needed to respond to stress and keep the body healthy. If you need treatment for more than a few days, or at high doses, your health care provider will gradually reduce the dose of [CV004 trade name] when stopping, so that your body has time to adjust.

It is important that you do not stop treatment suddenly yourself without consulting your health care provider. Talk to your health care provider if you have any concerns about your treatment.

4. Possible side effects

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

If any the following happen, tell your health care provider straight away:

- **Severe allergic reaction** – signs may include a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and feeling faint.
- **Severe infection** –if you get a severe infection, you may not get usual symptoms like rash or fever. If you feel unwell and are not getting better, or are getting worse, your health care provider can check you for infection.

The above reactions are not common but you may need urgent medical attention if either happens.

- **Mental health problems.** These can affect around 5 in every 100 people taking medicines like dexamethasone. Symptoms can include
 - Feeling depressed, including thinking about suicide
 - Feeling high (mania) or moods that go up and down
 - Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
 - Feeling, seeing or hearing things which do not exist
 - Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems, or if you are the carer of a patient using this medicine who shows any signs of mental problems, talk to a health care provider straight away. This is particularly important if depression or thoughts of suicide occur.

Many side effects of dexamethasone occur only with high doses or if treatment continues for a long period of time. As [CV004 trade name] is usually given for short-term treatment, they may be less likely with this medicine. Other side effects seen with dexamethasone are:

Common side effects (these may affect up to 1 in 10 patients):

- Picking up infections more easily
- Thrush (yeast infection) in the throat
- Reduced ability to produce natural corticosteroids, with symptoms such as tiredness and feeling unwell
- Cushing syndrome (excess corticosteroid) with signs such as weight gain, swelling of the face and between the shoulders, bruising and thinning of skin, purplish stretch marks
- High blood sugar (hyperglycaemia)
- Excessive eating
- Cataracts (clouding of the lens of the eye)
- Hot flashes
- Ulcer of the stomach or upper bowel (peptic ulcer)
- Slow healing of wounds
- Allergic symptoms such as redness, rash and swelling at the site of local injection
- Increased body hair
- Darkening of skin colour
- Hardening and thickening of skin (scleroderma)
- Fragile bones that break easily (osteoporosis)
- Muscle wasting

Uncommon side effects (these can affect up to 1 in 100 patients):

- Infection or allergic reaction in the area an injection is given
- Low blood counts of certain types of white blood cell (lymphopenia, eosinopenia)
- Missing menstrual periods (amenorrhoea)
- Low levels of potassium in blood tests (hypokalaemia)
- Inflammation of the pancreas (acute pancreatitis)
- Raised pressure inside the skull
- Seizures (fits) or worsening of epilepsy symptoms
- Heart failure (when the heart does not pump blood around the body well enough)
- Irregular heartbeats, palpitations (with injection into a vein)
- Blood clots obstructing veins (thromboembolism)
- Water retention and swelling (oedema)
- High blood pressure
- Reddening of face and cheeks
- Increased sweating
- Muscle weakness

Other side effects whose frequency cannot be established:

- Slowing of growth, bones not growing any more in children
- weight gain
- altered carbohydrate metabolism
- altered protein and calcium balance
- increased appetite
- salt and water retention
- fluid build-up under the retina of the eye (chorioretinopathy)
- thinning of the outer layers of the eye (cornea and sclera)
- visual disturbances, blurred vision

- irritation of the stomach and intestines
- perforation of the intestine
- acne
- thread veins (spider veins) in the skin
- death of bone tissue due to loss of blood supply (avascular necrosis)
- fractures in vertebrae or long bones
- rupture of tendons
- muscle damage (myopathy)
- temporary burning or tingling in the crotch area after injection of large doses into a vein
- deformity of bones and joints after injection into a joint (Charcot-like arthropathy)
- temporary worsening of symptoms after injection into a joint.

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [CV004 trade name]

Do not store above 25°C. Store in the original package in order to protect from light. Do not freeze. Avoid excursions above 25°C.

In-use: Diluted solution should be used within 24 hours when stored at 30°C.

Keep out of the reach and sight of children.

Do not use [CV004 trade name] after the expiry date which is stated on the carton and ampoule after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [CV004 trade name] contains

The active substance is dexamethasone phosphate. Each mL of the solution contains 4 mg dexamethasone phosphate.

The other ingredients are: sodium citrate, sodium hydroxide (pH adjusting agent), disodium edetate, creatinine, water for injections.

What [CV004 trade name] looks like and contents of the pack

Clear colourless or yellowish solution.

1 mL of solution is filled in a type 1 hydrolytic, amber glass ampoule with a break ring or break point. 5 or 10 such ampoules are packed in a carton.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>