

Potassium Chloride Oral Solution 10% – 20 mEq potassium/15 ml

Potassium Chloride Oral Solution 20% – 40 mEq potassium/15 ml

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.
- Ask your pharmacist if you need more information or advice.
- 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 Potassium Chloride Oral Solution is and what it is used for
2. What you need to know before you take Potassium Chloride Oral Solution
3. How to take Potassium Chloride Oral solution
4. Possible side effects
5. How to store Potassium Chloride Oral Solution
6. Contents of the pack and other information

1. What Potassium Chloride Oral Solution is and what it is used for

What is Potassium Chloride Oral Solution

Potassium Chloride Oral Solution contains a medicine called potassium chloride which is a potassium salt which your body needs to be healthy.

What is Potassium Chloride Oral Solution used for

Potassium Chloride Oral Solution is used to treat or to stop low levels of potassium in your body. If the level of potassium in your body is low, you will feel unwell.

How does Potassium Chloride Oral Solution work

It works by increasing the store of potassium in your body to the right level.

2. What you need to know before you take Potassium Chloride Oral Solution

- **Do not take potassium chloride oral solution if you:**
 - are **allergic** to potassium chloride, or any of the other ingredients of Potassium Chloride oral solution (listed in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat, or tongue.
 - have a severe kidney disorder with little or no urine production.
 - suffer from uncontrolled Addison's disease (where the adrenal glands do not produce enough of a hormone called cortisol).
 - Are dehydrated. You may feel thirsty or have a dry mouth.
 - have high potassium level (hyperkalemia) in your blood. Further increase in serum potassium concentration can produce cardiac arrest.
 - Have recently had serious burns
 - are on triamterene, amiloride. See section 2 “Other Medicines and Potassium Chloride Extended-Release Tablets”.
 - you have crush injuries (which usually result from major trauma e.g. major road traffic injuries with damage to the chest).

Do not take Potassium Chloride Oral Solution if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking it.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Potassium Chloride Oral Solution if you:

- have heart disease or you are taking digitalis (a drug for heart failure). See section 2 “Other medicines and potassium chloride oral solution”
- are taking ACE inhibitors (treatments for high blood pressure or heart failure e.g. captopril, enalapril and lisinopril). See section 2 “Other medicines and potassium chloride oral solution”
- have stiff_ muscles (myotonia congenital)
- have severe breakdown of red blood cells
- have a build-up of acid in your blood - your blood will need to be monitored
- have high blood pressure - your treatment may lower potassium level
- have a history of peptic ulcer. All oral potassium preparations should be prescribed with caution in patients with a history of peptic ulcer.
- have liver or renal Impairment.

If severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs, you should discontinue potassium chloride oral solution and call your doctor immediately.

Periodic blood tests and electrocardiograph (ECG) should be performed whilst you are taking potassium chloride oral solution.

Other Medicines and Potassium Chloride Oral Solution

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

In particular, the following medicines may interact with potassium chloride oral solution:

- triamterene or amiloride; concomitant use can produce severe high potassium level (hyperkalemia). Concomitant use with Potassium Chloride Oral Solution is contraindicated. See section 2 “Do not take Potassium Chloride Oral Solution”
- digitalis (a drug for heart failure), Potassium supplements should be used with caution in diseases associated with heart block, since increased serum potassium may increase the degree of heart block
- Nonsteroidal anti-inflammatory drugs, Renin-Angiotensin-Aldosterone inhibitors including ACE inhibitors and ARBs (treatments for high blood pressure or heart failure), cyclosporine, heparin, beta-blockers: Simultaneous administration of these agents with potassium chloride oral solution can produce severe high potassium level (hyperkalemia). It may still be all right for you to be given potassium chloride oral solution and your doctor will be able to decide what is suitable for you. See section 2 “Warnings and precautions”

If you are taking any of these medicines (or are not sure) talk to your doctor or pharmacist before taking Potassium Chloride Oral Solution.

Taking potassium chloride oral solution with Food and Drink

The interaction of Potassium Chloride Oral Solution has not been studied with regards to food.

Pregnancy and Breast-feeding

Pregnancy

There are no human data related to use of Potassium Chloride Oral Solution during pregnancy, and animal reproduction studies have not been conducted. Potassium supplementation that does not lead to hyperkalemia is not expected to cause fetal harm.

Do not take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby unless your doctor advises it is essential.

Breast-feeding

Since oral potassium becomes part of the body potassium pool, as long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

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.

Driving and Using Machines

Potassium Chloride Oral Solution should have no effect on your ability to drive or use machines.

3. How to take Potassium Chloride Oral Solution

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

Dosage

Dosage will be adjusted to the individual needs of each patient. Dosages greater than 40 mEq per day should be divided such that no more than 40 mEq is given in a single dose.

Your doctor will monitor your serum potassium and adjust dosages accordingly.

Treatment of low potassium level (Hypokalemia):

Adult:

Typical dose range is 40 to 100 mEq per day in 2 – 5 divided doses. Maximum is 200 mEq in 24-hour period.

Children aged birth to 16 years old:

Initial dose is 2 – 4 mEq/kg/day in divided doses, The dose should not exceed as a single dose 1 mEq/kg or 40 mEq, whichever is lower; maximum daily doses should not exceed 100 mEq.

Maintenance or Prophylaxis:

Adult: Typical dose range is 20 mEq per day.

Children: aged birth to 16 years old: Typical dose is 1 mEq/kg/day. Do not exceed 3 mEq/kg/day.

Method and/or Route(s) of Administration

You should not take potassium chloride oral solution undiluted. Dilute the potassium chloride solution with at least 4 ounces of cold water to minimize its gastric irritation effect.

Take it with meals or immediately after eating.

If you take more Potassium Chloride Oral Solution than you should

Go to the nearest emergency department or contact your doctor immediately. Take your oral solution container with you.

If you forget to take Potassium Chloride Oral Solution

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking or using Potassium Chloride Oral Solution

Do not stop taking this medicine without first talking to your doctor. If you stop taking this medicine suddenly, your condition may become worse.

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away If you get:

- any sudden wheeziness
- difficulty in breathing
- swelling of the eyelids, face or lips
- rash or itching (especially affecting your whole body)

Side effects include:

Rare (may affect up to 1 in 1000 people)

- Feeling or being sick
- Diarrhea
- Abdominal cramps
- High level of potassium in people that have familial hyperkalemic periodic paralysis.
- Stomach or food pipe (esophagus) irritation
- Abdominal (tummy) discomfort.

Reporting of Side Effects

If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system of SFDA. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to Store Potassium Chloride Oral Solution

- 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 pack after EXP. The expiry date refers to the last day of that month.
- Store at 20° to 25°C.
- Store in the original container and keep the container tightly closed to protect from light and moisture.
- 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 to protect the environment.

6. Contents of the pack and other information

What Potassium Chloride Oral Solution contains

- Potassium Chloride Oral Solution 10%
 - Active Substance is potassium chloride
Each 1ml contains 100mg potassium chloride “1.5 g/15ml” (equivalent to 1.3 mEq of potassium per ml)
 - The other ingredients are:
Citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, natural/artificial orange flavor, propylene glycol, propylparaben, purified water, sucralose, trisodium citrate dihydrate.
- Potassium Chloride Oral Solution 20%
 - Active Substance is potassium chloride
Each 1ml contains 200mg potassium chloride “3 g/15ml” (equivalent to 2.6 mEq of potassium per ml)
 - The other ingredients are:

Citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, natural/artificial orange flavor, propylene glycol, propylparaben, purified water, sucralose, trisodium citrate dihydrate.

What Potassium Chloride Oral Solution looks like and contents of the pack

Potassium Chloride Oral Solution 10% : is light yellow to yellow colored solution with orange flavor. Available in bottles of 473 ml.

Potassium Chloride Oral Solution 20%: is light yellow to yellow colored solution with orange flavor. Available in bottles of 473 ml.

Marketing Authorisation Holder

Granules Pharmaceuticals Inc.
3701 & 3725 Concorde Parkway,
Chantilly, Virginia (VA) 20151,
United States (USA)

Manufacturer

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Chantilly, Virginia (VA) 20151,
United States (USA)

This leaflet was last revised in (mm/yyyy)

– **To reports any Side Effect(s):**

- Saudi Arabia

- The National Pharmacovigilance and Drug Safety Centre (NPC):
 - o SFDA Call Center: 19999
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: <https://ade.sfd.gov.sa/>

- Other GCC States:

- Please contact the relevant competent authority

This is a Medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

& Union of Arab Pharmacist