

FRAKAS

Doxycycline monohydrate Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FRAKAS.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FRAKAS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What FRAKAS is used for

FRAKAS is used to:

- treat infections
- control acne
- prevent a form of malaria.

FRAKAS is an antibiotic and belongs to a group of medicines called tetracyclines. These medicines work by killing or stopping the growth of bacteria which cause infections or make acne worse. They also work against parasites that cause malaria. Tetracyclines will not work against viral infections such as colds or flu.

Your doctor may have prescribed FRAKAS for another reason. Ask your doctor if you have any questions about why FRAKAS has been prescribed for you.

FRAKAS is available only with a doctor's prescription.

There is no evidence that FRAKAS is addictive.

Before you take FRAKAS

When you must not take it

Do not take FRAKAS if you are allergic to medicines containing doxycycline or any other tetracycline medicine or any of the ingredients listed at the end of this leaflet.

Do not take FRAKAS if you are taking preparations containing Vitamin A, isotretinoin or etretinate. Ask your doctor or pharmacist if you are not sure if you are taking one of these medicines.

Do not take this medicine if you are more than 18 weeks pregnant or are breastfeeding.

As with many medicines, tetracyclines may harm your developing or breast-feeding baby. Tetracyclines may cause enamel loss and staining of your child's teeth or increase the pressure on your child's brain. High doses of tetracyclines may also cause liver problems in pregnant women.

Do not take FRAKAS if the expiry date (Exp.) printed on the pack has passed.

Do not take FRAKAS if the packaging is torn or shows signs of tampering.

Do not give FRAKAS to children under 8 years of age. Doxycycline like other tetracyclines, may cause enamel

loss and staining in developing teeth. It may also cause increased pressure on the brain if used in infants.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you are breastfeeding or wish to breastfeed.

If you have not told your doctor about any of the above, tell him/her before you start taking FRAKAS.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by FRAKAS, or may affect how well it works. These include:

- preparations containing Vitamin A
- some medicines used for skin problems such as isotretinoin or etretinate
- warfarin, a medicine used to stop blood clotting
- methoxyflurane, an inhaled anaesthetic
- the contraceptive (birth control) pill. FRAKAS may decrease the effectiveness of some birth control pills. Your doctor may advise you to use an additional method of contraception while you are taking FRAKAS.

- another group of antibiotics called penicillins
- barbiturates such as phenobarbitone
- anticonvulsant medicines that are used to treat seizures, such as phenytoin and carbamazepine
- sodium bicarbonate
- acetazolamide, a medicine used to treat glaucoma

Some medicines may interfere with the absorption of FRAKAS. These include:

- iron preparations including vitamin preparations that contain iron
- antacids used for indigestion.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking FRAKAS.

How to take FRAKAS

How much to take

For treating infections, the usual dose of FRAKAS is two 100 mg tablets on the first day followed by one 100 mg tablet each day from then on.

For controlling acne, the usual dose of FRAKAS is one 50 mg tablet each day.

For the prevention of malaria, the usual dose FRAKAS is one 100 mg tablet each day, commencing two days before entering the malarious area, during the visit, and for two weeks after leaving the area. FRAKAS is normally used in combination with another antimalarial medicine.

Depending on your condition and how you react to the medicine, your

doctor may ask you to take a different dose.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take FRAKAS

Swallow the tablets whole with a full glass of water or milk while sitting or standing upright. Do not lie down for at least half an hour after swallowing your tablet. This is to help avoid irritation to your food pipe, also called the oesophagus.

Take FRAKAS during or immediately after a meal, at about the same time each day (usually in the morning).

If taken on an empty stomach, it may cause stomach upset.

If you forget to take FRAKAS

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take FRAKAS for

Do not stop taking FRAKAS because you are feeling better.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing the infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or may return.

For treating infections, FRAKAS is usually taken for one or two weeks.

For controlling acne, FRAKAS is usually taken for a period up to 12 weeks.

For preventing malaria, FRAKAS is normally recommended to be taken up to a maximum of 8 weeks.

However, your doctor may prescribe FRAKAS for longer periods.

If you take too much FRAKAS (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much FRAKAS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking FRAKAS

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking FRAKAS.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FRAKAS.

If you become pregnant while taking FRAKAS, tell your doctor.

If you are taking FRAKAS for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking FRAKAS.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Do not take any diarrhoea medicine without first checking with your doctor.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

If you are taking iron preparations, including vitamins

that contain iron or antacids (containing aluminium, calcium or magnesium), you must take them at least two hours before or two hours after this medicine, to make sure there is no problem with absorption.

Things you must not do

Do not stop taking FRAKAS because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or may return.

Do not use FRAKAS to treat any other conditions unless your doctor tells you to.

Do not give FRAKAS to anyone else, even if they have the same condition as you.

Things to be careful of

Protect your skin when you are in the sun, especially between 10 am and 3 pm.

FRAKAS may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn.

If outdoors, wear protective clothing and use a 30+ sunscreen. If your skin does appear to be burning, stop taking FRAKAS and tell your doctor as soon as possible.

If you get thrush (a fungal infection which can affect the mouth and/or vagina) or any other infection while taking, or soon after stopping FRAKAS, tell your doctor.

Sometimes the use of this medicine allows fungi to grow as they are not killed by FRAKAS.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FRAKAS.

Like all other medicines, FRAKAS may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore itchy vagina and/or discharge
- rash or itching
- nail changes
- stomach upset or vomiting
- difficulty in swallowing
- sore mouth or tongue
- mild irritation of the food pipe
- taste loss
- ringing or other persistent noise in the ears

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- depression
- feeling anxious or nervous
- muscle tenderness or weakness, not caused by exercise
- painful swollen joints

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- increased pressure in the brain (headache, blurred vision, vomiting)

- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- severe skin reactions starting as painful red areas then larger blisters and ends with peeling layers of skin
- difficulty swallowing
- pain when swallowing
- flaking of the skin
- dizziness
- fast heart rate
- frequent bruising
- passing less urine
- yellowing of the eyes or skin (jaundice)
- severe upper stomach pain often with nausea and vomiting (pancreatitis)
- symptoms of an allergic reaction such as shortness of breath, wheezing or troubled breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- a rare, potentially life-threatening, drug-induced sensitivity reaction that includes skin rashes, blood changes, fever and dysfunction of internal organs (eg. Liver, kidney, lung)
- a reaction that can happen after starting FRAKAS therapy for a particular bacterial infection (spirochete infections, eg. Lyme disease); symptoms include fever, chills, muscle pain or worsening of skin rash

These are serious side effects. You may need urgent medical attention or hospitalisation.

After finishing it

Tell your doctor immediately you notice any of the following side effects, particularly if they occur several weeks after stopping FRAKAS:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may be bloody

- fever in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. FRAKAS can cause some bacteria that are normally harmless and present in the bowel to multiply and cause the above symptoms. Therefore you may need urgent medical attention.

Do not take any medicine for diarrhoea without first checking with your doctor.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using FRAKAS

Storage

Keep FRAKAS where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store FRAKAS or any other medicine in the bathroom or near a sink.

Do not leave FRAKAS in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking FRAKAS, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

FRAKAS is a dull yellow, round, biconvex tablet.

Each pack contains 25 tablets.

Ingredients

The active ingredient in FRAKAS is doxycycline. Each FRAKAS tablet contains 50 mg of doxycycline.

The tablets also contain:

- microcrystalline cellulose
- sodium starch glycollate type A
- hydrogenated castor oil
- povidone
- colloidal anhydrous silica
- magnesium stearate.

Supplier

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Telephone: 1800 726 369

Frakas is distributed in Australia by:

Aspen Pharma Pty Ltd
34-36 Chandos Street
St. Leonards
NSW 2067

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