

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some common questions about Frakas.

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

All medicines have risks and benefits. 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, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

### What Frakas is used for

The name of your medicine is Frakas. It contains the active ingredient doxycycline (as doxycycline monohydrate).

Frakas is used for treating infections, controlling acne, and preventing a form of malaria.

Your doctor may have prescribed Frakas for another reason. Ask your doctor if you have any questions about why Frakas was prescribed for you.

### How Frakas works

**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.**

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 the active ingredient, other tetracyclines or any of the inactive ingredients mentioned at the end of this leaflet under Product Description.
  - You are pregnant or breast-feeding, or if there is a possibility that pregnancy may occur. Frakas, like other tetracyclines, may harm the developing or breastfeeding baby. This may include enamel loss and staining of the child's teeth. High doses of tetracyclines may also cause liver problems in pregnant women.
- If you are a woman of childbearing age, you should avoid becoming pregnant while taking Frakas by using adequate contraception.**
- You are taking preparations containing vitamin A or retinoids, isotretinoin (eg. Roaccutane®) or etretinate (eg. Tigason®).
  - **Children:** Do not give Frakas to children of eight years and under unless directed by the child's doctor. Frakas, like other tetracycline, may cause enamel loss and staining in developing teeth.
  - It is past its expiry date or the packaging appears to have been tampered with.

#### *Before you start to take Frakas*

Tell your doctor if you have allergies to:

- Any other medicines.

- Any other substances, including foods, preservatives or dyes.

Tell your doctor if you plan on becoming pregnant or will be breast feeding while you are using Frakas.

Tell your doctor if you have or have had any health problems.

#### **Taking other medicines**

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

In particular, tell your doctor if you take any of the following:

- Preparations containing vitamin A.
  - Some medicines used for skin problems such as isotretinoin or etretinate.
  - Warfarin, a medicine used to stop blood clotting.
  - Another group of antibiotics called penicillins.
  - The contraceptive pill (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 taking Frakas.**
- Some medicines used in the treatment of epilepsy such as phenytoin, carbamazepine or phenobarbitone.

These medicines may be affected by Frakas, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

- Iron preparations including vitamin preparations that contain iron.
- Antacids used for indigestion.

You can still take these medicines while you are taking Frakas. However, you must take Frakas at least two hours before or two hours after taking any of these medicines to make sure there is no problem with absorption.

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## How to take Frakas

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Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

### *How much to take*

#### **For treating infections, the usual dose of Frakas is:**

- 200 mg (4 x 50 mg tablets) on the first day followed by 100 mg (2 x 50 mg tablets) each day from then on.

#### **For controlling acne, the usual dose is:**

- 50 mg (1 x 50 mg tablet) each day.

#### **For the prevention of malaria, the usual dose is:**

- 100 mg (2 x 50 mg tablets) each day, commencing two days before entering the malarious area, during the visit, and two weeks after leaving the area. Frakas is normally used in combination with other antimalarial medicine.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose. Do NOT take any more than prescribed by your doctor.

### *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.**

### *When to take it*

**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.

### *How long to take it*

**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 forget to take your dose*

Take your dose as soon as you remember, and continue to take it as you would normally.

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

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.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### *If you take too much*

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Frakas.

Do this even if there are no signs of discomfort or poisoning.

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## While you are taking Frakas

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### *Things you must do*

- Always follow your doctor's instructions carefully.
- 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 Frakas has been stopped. 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.
- Tell your doctor immediately if you become pregnant while taking Frakas.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Frakas.

### *Things you must not do*

- Do not stop taking Frakas without your doctor's permission.
- Do not use Frakas to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their

symptoms seem similar to yours.

### **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 15+ sunscreen. If your skin does appear to be burning, stop taking Frakas and tell your doctor.

If you get thrush (a yeast infection which can affect the mouth and /or vagina) or any other infection while taking, or soon after stopping Frakas, tell your doctor. Sometimes use of this medicine allows yeast and some microbes, which are not killed by Frakas, to grow.

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### **Side effects**

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All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

#### **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 and itchy vagina and /or discharge.

#### **The most common side effects seen in patients taking doxycycline are:**

- Sun/light induced dermatitis; skin rashes, urticaria and discolouration of the nail.
- Nausea, vomiting, dysphagia, diarrhoea, oesophageal irritation and ulceration, abdominal pain.
- Tooth discolouration.

Less common side effects such as enterocolitis, inflammatory lesions in the ano-genital region; exfoliative

dermatitis, malaise, and confusion have been reported.

Inform your doctor if any of these side effects occur.

#### **If any of the following happen, stop taking Frakas and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

This is a very serious side effect. You may need urgent medical attention or hospitalisation. This is a very rare side effect.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

#### **After finishing it**

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with 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. Therefore, you may need urgent medical attention. However, this side effect is rare.

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

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### **After using Frakas**

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#### **Storage**

Keep Frakas in the original packaging until you need to take it. Store below 25°C in a dry place, and out of the reach of children.

### **Disposal**

Return any unused or out of date medicine to your pharmacist.

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### **Product description**

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#### **What it looks like**

Frakas 50 mg tablet is a dull yellow, round, biconvex tablet. They are available in blister packs of 25 tablets.

#### **Ingredients**

As well as the active ingredient, Frakas also contains some inactive ingredients cellulose microcrystalline, sodium starch glycollate, hydrogenated castor oil, povidone, colloidal silicon dioxide, and magnesium stearate.

#### **Manufacturer**

Hexal Australia Pty Ltd  
Level 4, 100 Harris St  
Pymont NSW 2009  
**Tel: 18000 HEXAL**  
www.hexal.com.au

#### **Supplier**

Sigma Pharmaceuticals (Australia) Pty Ltd  
96 Merrindale Drive  
Croydon Vic 3136  
Tel: 03 - 9839 2800

Date of preparation:  
July 2009

#### **Australian Register Number**

Frakas 50 mg tablets: AUST R 98653