

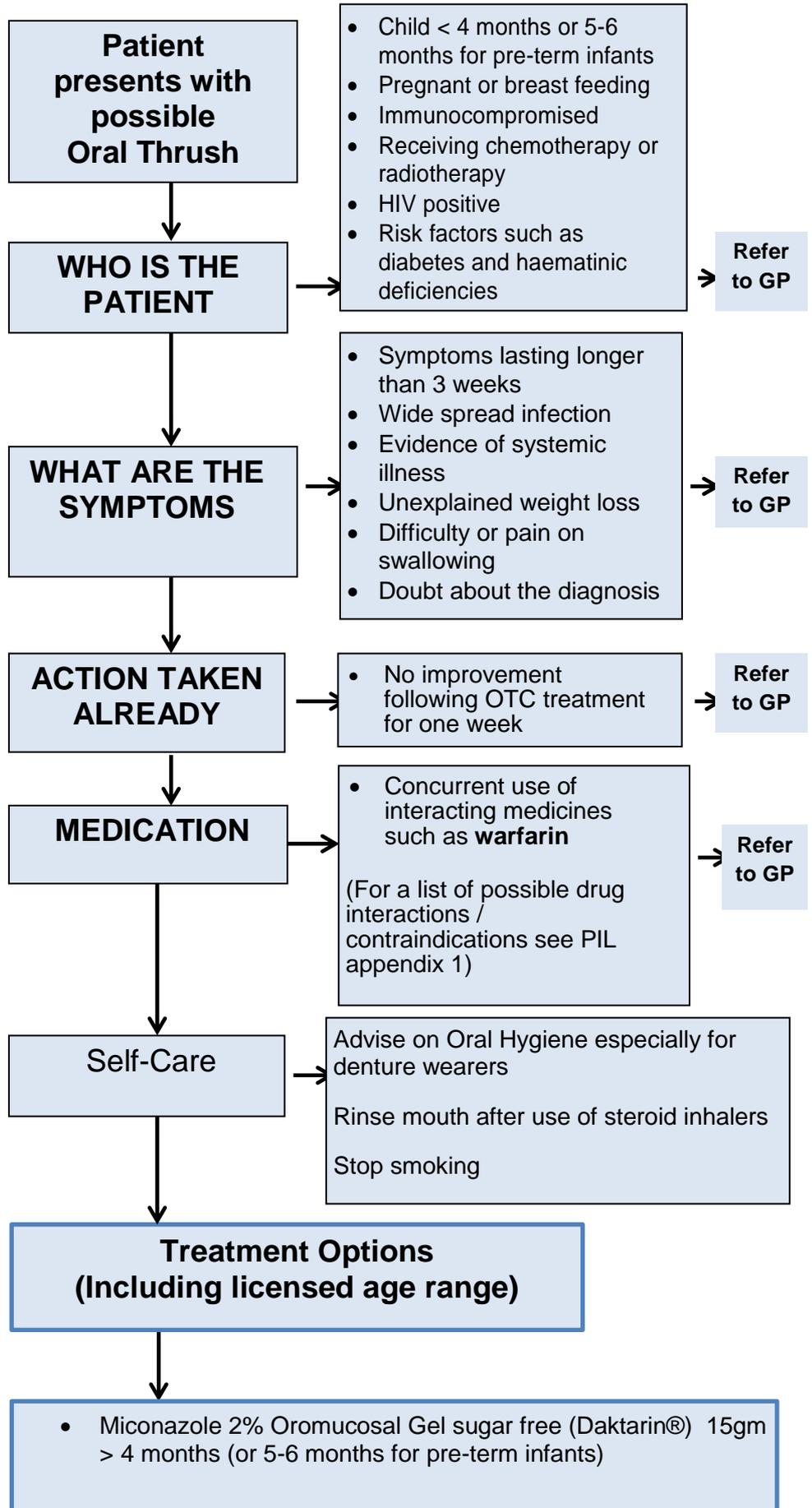
Oral thrush is a fungal infection of the oral mucosa caused by *Candida* species. It is the most common human fungal infection. It is uncommon in people other than infants, denture wearers and the elderly. In otherwise healthy people, oral thrush may be the first presentation of an undiagnosed risk factor, such as HIV infection, cancer, diabetes, anaemia.

Candida may also occur in people who are treated with inhaled corticosteroids for asthma or rhinitis, in immunocompromised patients and following a course of antibiotics.

Thrush occurs in up to 2-5% of newborns as it is acquired from their mothers at birth and may appear as early as 7-10 days old. Use of antibiotics especially in the first year of life may lead to recurrent infection. It is uncommon in children older than 1 year old unless related to antibiotic use, those who are immunocompromised or steroid inhaler use without mouth rinsing post-use.

Symptoms

- Superficial, white/yellow curd-like areas on lips, buccal mucosa, tongue and/or palate, which can be easily removed to reveal an underlying red base that, is not usually painful.
- Removal of plaques may cause mild bleeding which helps confirm diagnosis.
- May cause cracked, red, moist areas on skin at the corners of the mouth.
- May be asymptomatic or may cause pain.
- May cause a cottony feeling in the mouth and loss of taste.
- May cause restlessness and a decrease in feeding in infants.
- Under denture plates may manifest as erythema with no plaques.



Advice for Self-Care / Non Pharmaceutical Treatment	Treatment Options Formulary Items		
	Drug	Dose and Duration	Advice
<p>Lifestyle advice to aid healing and prevent recurrence</p> <ul style="list-style-type: none"> • If the person is a smoker, offer advice on smoking cessation. • If the person is using an inhaled corticosteroid, advise the following: good inhaler technique; rinsing the mouth with water (or cleaning the teeth) after inhalation, to remove any drug particles; using a spacer device to reduce the impaction of particles in the oral cavity; and stepping down the dose of inhaled corticosteroid when appropriate. • Advise on good dental hygiene. Brush teeth regularly with a soft toothbrush. • If the person wears dentures, advise them to: <ul style="list-style-type: none"> - Leave the dentures out for at least 6 hours in each 24-hour period to promote healing of the gums. If the gums are inflamed, they may benefit from the dentures being left out for longer. - Clean dentures by brushing and then soaking them in a disinfectant solution overnight. - Allow the dentures to air-dry after disinfection — this also kills adherent Candida. - Brush the mucosal surface regularly with a soft brush. - See a dentist to correct ill-fitting dentures. • Do not use OTC mouthwashes or sprays as they may alter normal oral flora • Eating unsweetened yoghurt may help restore the normal oral bacterial flora • If the person has diabetes, refer to GP for review of diabetic control and appropriate management, particularly if there are recurrent episodes of oral candidiasis. <ul style="list-style-type: none"> - For people taking a sulphonylurea (such as gliclazide), be aware of drug interactions with miconazole. 	<p>Adults and Children over 4 months:</p> <p>Miconazole Oral Gel 2%</p>	<p>Infants 4-24 months: 1.25 ml (1/4 measuring spoon) applied 4 times a day after meals. Each dose should be divided into smaller portions and applied to the affected area(s) with a clean finger. Do not apply to the back of the throat due to possible choking. The gel should not be swallowed immediately, but kept in the mouth as long as possible.</p> <p>Adults and Children 2 years of age and over: 2.5 ml (1/2 measuring spoon) applied 4 times a day after meals. The gel should not be swallowed immediately, but kept in the mouth as long as possible.</p>	<p>To be administered after food and retained near oral lesions before swallowing.</p> <p>When treating infants younger than 6 months, avoid placing gel near to back of tongue to avoid choking.</p> <p>The treatment should be used for 7 days and continued for at least a week after the symptoms have disappeared</p>

References: Clinical Knowledge Summaries: Oral Thrush <https://cks.nice.org.uk/candida-oral#>

See individual SPC for further information/advice

Reviewed January 2018 - HSCB

Daktarin[®] oral gel

Miconazole

Daktarin is a registered trademark

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

- 1 What Daktarin oral gel is and what it is used for**
 - 2 Before you use Daktarin oral gel**
 - 3 How to use Daktarin oral gel**
 - 4 Possible side effects**
 - 5 How to store Daktarin oral gel**
 - 6 Further information**
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1 What Daktarin oral gel is and what it is used for

Daktarin oral gel is a medicine which is used to treat fungal infections of the mouth, throat, gullet, stomach or gut. The gel contains miconazole which works by destroying the fungus that is present.

This medicine is for use in adults and children aged 4 months and over.

2 Before you use Daktarin oral gel

Do not use Daktarin oral gel:

- If you are allergic to miconazole, any of the other ingredients of this medicine (listed in section 6) or to other similar antifungal medicines
- If you suffer from liver problems
- If it is for an infant under 4 months of age because of risk of choking.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Daktarin oral gel.

Take special care with Daktarin oral gel

Daktarin oral gel is sticky. This ensures that it stays in the mouth for as long as possible. If you are giving the gel to a child or infant, make sure that the gel does not close off the child's or infant's throat as they could choke on it. You should place the gel at the front of the mouth – never put it at the back of the throat. If your infant is being treated with Daktarin oral gel, and you are breast-feeding, do not apply the gel to your nipple in order to give the gel to your infant.

Blood tests

If you are also taking medicines to thin the blood (anticoagulants, such as warfarin) or if you are taking phenytoin (a medicine for epilepsy), your doctor may want to check the level of the medicines in your body by testing your blood.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not take this medicine and tell your doctor if you are taking any of the following medicines:

- Medicines for hay fever or allergy called terfenadine, astemizole or mizolastine
- Cisapride – for digestive problems
- Medicines to lower cholesterol called lovastatin or simvastatin
- Midazolam (by mouth) or triazolam - for anxiety or to help you sleep
- Pimozide or sertindole - for conditions affecting thoughts, feelings and behaviour
- Medicines for an irregular heart beat called quinidine or dofetilide
- Ergotamine - used to treat migraine.

Do not start using Daktarin oral gel and tell your doctor if you are taking any of the above.

Tell your doctor or dentist before taking, or if you are already taking, any of the following medicines:

- Medicines to thin the blood (anticoagulants) such as warfarin.

- Medicines for HIV infection such as saquinivir. They are called 'antiviral protease inhibitors'
 - Medicines used in the treatment of cancer such as busulfan, docetaxel and a group of medicines known as 'vinca alkaloids'
 - Medicines that act on the heart and blood vessels called 'calcium channel-blockers' such as dihydropyridines and verapamil
 - Medicines that are usually given after an organ transplant called cyclosporin, tacrolimus or rapamycin. Another name for rapamycin is sirolimus
 - Medicines for epilepsy called phenytoin or carbamazepine
 - Alfentanil - for pain
 - Medicines used for anxiety or to help you sleep (tranquillisers), such as buspirone, alprazolam or brotizolam
 - Midazolam - to help you relax or sleep when given into a vein
 - Rifabutin - for tuberculosis
 - Methylprednisolone - for inflammation (given by mouth or injection)
 - Ebastine - for allergy
 - Reboxetine - for depression
 - Sulphonylureas such as chlorpropamide and glibenclamide (medicines for diabetes taken by mouth)
 - Sildenafil – for erection problems
 - Trimetrexate – for a type of pneumonia
- Tell your doctor or dentist before taking, or if you are already taking any of the above. They may need to alter your treatment.

Pregnancy and breast-feeding

Please tell your doctor before using Daktarin oral gel if you are pregnant, think you may be pregnant or might become pregnant.

You may still be able to use Daktarin oral gel if your doctor thinks you need to.

Talk to your doctor before using this medicine if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Daktarin oral gel is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Daktarin oral gel

- Daktarin oral gel contains small amounts of ethanol (alcohol), less than 100 mg per dose.

3 How to use Daktarin oral gel

Always use Daktarin oral gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to apply the gel

- Each tube of the gel is sealed - use the cap to pierce the seal
- For oral use only
- Keep the gel in the mouth as long as possible. Do not swallow it straight away
- If the infection is just in the mouth, apply directly to the affected area with a clean finger
- If you are wearing dentures, remove them at bedtime and rub them with the gel. This helps stop your dentures becoming infected too
- Do not use more than the stated dose
- Use after meals
- If you are giving the gel to a child or infant aged 4 months or over, make sure that the gel does not become a **choking hazard** by making sure you **place the gel at the front of the mouth**

When to stop using Daktarin oral gel

Keep using the gel for at least a week after all the symptoms have gone away. This will stop the symptoms from coming back.

If you forget a dose

- Do not apply the missed dose of gel
- Apply the next dose of gel as usual and keep using it as your doctor has told you
- Do not use a double dose of gel to make up for a missed dose

How much gel to use

Your doctor will tell you how much Daktarin oral gel to take and for how long you should take it. Your doctor will probably suggest the following treatment course:

Infections of the mouth and throat:

- **Adults and Children over 2 years:** 2.5 ml (half a 5ml spoonful) of gel applied four times a day after food.
- **Infants 4 months - 2 years:** 1.25 ml (one quarter of a 5 ml spoonful) of gel applied four times a day after food. Each application should be divided into smaller portions.

Infections of the stomach and gut:

- **Adults, Children and infants over 4 months:** 20 mg per kg of body weight per day. Divided into four doses a day. Maximum dose is 10 ml of gel four times a day.

If the infant is 4-6 months old and is premature or has slow development check with your doctor before using this medicine.

If symptoms persist, talk to your doctor.

If you use more Daktarin oral gel than you should

If you use more Daktarin oral gel than you were told to or if someone else has taken any, talk to a doctor or go to the nearest hospital casualty department straight away.

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

4 Possible side effects

Like all medicines, Daktarin oral gel can cause side effects, although not everybody gets them.

Stop using Daktarin oral gel and tell your doctor straight away if you notice the following. You may need medical treatment.

- Sudden swelling of the face, lips, tongue or throat; difficulty swallowing; hives (also known as nettle rash or urticaria) and breathing difficulties (angioedema, anaphylactic reactions); severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction.
- Severe skin disorders with peeling and/or rashes with small pus-containing pimples (with a fever) or blistering of your skin, mouth, eyes and genitals (toxic epidermal necrolysis or Stevens-Johnson Syndrome)
- Light headedness, generalised itch, wheezing or difficulty breathing.
- If you are taking medicines to thin the blood (anticoagulants), such as warfarin: unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit.

Other side effects which may occur:

Common (affects 1 to 10 users in 100)

- Dry mouth
- Feeling sick (nausea)
- Being sick (vomiting)
- Mouth discomfort
- Regurgitation
- Product tastes abnormal

Uncommon (affects 1 to 10 users in 1,000)

- Loss or abnormal sense of taste

The following side effects were also seen in a small number of patients

- Choking
- Diarrhoea
- Inflammation of the liver (hepatitis)
- Sore mouth
- Tongue discolouration
- Rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5 How to store Daktarin oral gel

Keep out of the reach and sight of children.

Store the gel in its original packaging.
Do not store above 30°C.

Do not use Daktarin oral gel after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6 Further information

The active substance in Daktarin oral gel is miconazole. Each gram (g) of Daktarin oral gel contains 20 milligrams (mg) of miconazole.

The other ingredients are pregelatinised potato starch, alcohol, polysorbate 20 (E432), sodium saccharin, cocoa flavour, orange flavour, glycerol and water.

What Daktarin oral gel looks like and contents of the pack

Daktarin oral gel comes in a tube containing 80 g of a white, sugar free gel with an orange flavour. A 5 ml plastic spoon, marked with a 2.5 ml graduation is provided.

The product licence is held by:
JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

Daktarin oral gel is made by:

Janssen Pharmaceutica NV,
Turnhoutseweg 30, B-2340 Beerse,
Belgium

OR

McGregor Cory Ltd, Middleton Close,
Banbury, OX16 4RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.

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Janssen 