CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET: ORALACT

SCHEDULING STATUS: **S2**

ORALACT 0,74 mg/ml Mouthwash

Diclofenac free acid

Sugar free

Contains sweetener: Acesulfame 1 mg/ml

Contains sugar alcohol: Sorbitol 0,5 g/ml

Preservative: Sodium benzoate 1 % *w/v*

Read all of this leaflet carefully before you start using ORALACT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Do not share ORALACT with any other person.
- Unless you are treating painful conditions of the mouth caused by cancer treatment (radiotherapy), you must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What ORALACT is and what it is used for
2. What you need to know before you use ORALACT
3. How to use ORALACT
4. Possible side effects
5. How to store ORALACT
6. Contents of the pack and other information

1. What ORALACT is and what it is used for

ORALACT belongs to the group of medicines called non-steroidal anti-inflammatory drugs or NSAIDS.

ORALACT works by stopping pain and swelling (inflammation).

It is used to treat many painful conditions of the mouth or throat including:

- Sore throat;
- inflammation and ulceration of the mucous membranes lining the mouth, gums, tongue and throat (often a complication of cancer treatment);
- discomfort associated with dentures, dental treatment or extraction.

2. What you need to know before you use ORALACT

Do not use ORALACT:

If you are hypersensitive (allergic) to diclofenac, acetylsalicylic acid (aspirin), other non-steroidal anti-inflammatory drugs (NSAIDs), or any of the other ingredients of ORALACT (listed in section 6).

Warnings and precautions

Take special care with ORALACT:

Stop using ORALACT if you experience fever, rash, facial swelling, enlarged lymph nodes, kidney or liver injury, or have blood test results which indicate an abnormal level of blood cells called eosinophils.

The use of topical preparations, such as ORALACT, especially for long periods of time, can cause the development of sensitisation phenomena (becoming more sensitive to the effects of ORALACT). In this case, stop using DICORAL and contact your doctor.

Other medicines and ORALACT

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The use of ORALACT during pregnancy and breastfeeding is not recommended.

Driving and using machines

It is not always possible to predict to what extent ORALACT may interfere with your daily activities. You should ensure that you do not execute tasks or activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment until you are aware of the measure to which ORALACT affects you.

ORALACT contains sorbitol

Sorbitol is a sugar alcohol and as a result ORALACT may have a laxative effect. In addition, if you have been told that you have an intolerance to some sugars, you should not take ORALACT.

ORALACT contains sodium benzoate

Sodium benzoate is a mild irritant of the skin, eyes and mucous membranes.

3. How to use ORALACT

Do not share medicines prescribed for you with any other person.

Always use ORALACT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

<u>The recommended dose in adults:</u>

Treatment of painful, inflammatory conditions of the oropharyngeal cavity (mouth and throat):

Rinse or gargle with 15 ml of solution for 30 seconds twice a day.

Treatment of pain and inflammation resulting from minor dental treatment or extraction:

Rinse or gargle with 15 ml of solution for 1 minute twice a day.

Treatment of pain and inflammation due to oral mucositis following radiotherapy in oncology (cancer) patients:

Rinse or gargle with 15 ml of solution for 2 minutes three times a day.

The required quantity of solution (undiluted or diluted in a small amount of water) should be rinsed around the mouth or used as a gargle and then spat out.

The solution should not be swallowed.

Unless you are treating painful conditions of the mouth caused by cancer treatment (radiotherapy), if your symptoms worsen or do not improve after 7 days, please contact your doctor, pharmacist or other healthcare professional.

If you have the impression that the effect of ORALACT is too strong or too weak, tell your doctor or pharmacist.

If you use more ORALACT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Accidental swallowing of the solution poses no known risks.

If you forget to use ORALACT

If you forget a dose, take it as soon as you remember.

However, if it is nearly time for the next dose, skip the missed dose. Then continue with your normal schedule.

Do not take a double dose to make up for forgotten individual doses.

If you have missed several doses, consult your doctor.

4. Possible side effects

ORALACT can have side effects.

Not all side effects reported for ORALACT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ORALACT, please consult your healthcare provider for advice.

If any of the following happens, stop using ORALACT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- skin rash, lesions, itchiness of the skin, blistering or peeling of the skin or any other type of skin irritation; or
- chest tightness, difficulty breathing, feeling dizzy or fainting due to low blood pressure.

These are all very serious side effects. If you have them, you may have had a serious reaction to ORALACT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Mild irritation of the oral mucosa;
- cough.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or healthcare professional. This includes any possible side effects not listed in this leaflet. You can report side effects to Actor Pharma (Pty) Ltd via email: pharmacovigilance@actorpharma.co.za or telephonically on 011 312 3812. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ORALACT.

5. How to store ORALACT

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Store in the original packaging to protect from light and moisture.

Keep the container in the outer carton.

Keep the bottle tightly closed.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the bottle and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ORALACT contains

The active substance is diclofenac free acid.

Each 1 ml of solution contains 0,74 mg diclofenac free acid.

The other ingredients are choline solution, sorbitol, sodium benzoate, disodium edetate, acesulfame potassium, peach flavouring agent, peppermint oil, ponceau red E124, purified water.

What ORALACT looks like and contents of the pack

Mouthwash

Clear or slightly opalescent red-orange solution with characteristic peach and mint flavour.

The solution is supplied in a 200 ml transparent amber type 3 glass bottle closed with a plastic child-proof screw cap. Packaged with a 15 ml polypropylene measuring device.

The glass bottle is contained in a cardboard carton.

Holder of certificate of registration

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Access to the corresponding professional information

The corresponding Professional Information is available electronically on www.actorpharma.co.za.

Alternatively, to obtain this Professional Information please contact Actor Pharma (Pty) Ltd on 011-312 3812 or email info@actorpharma.co.za.

[1] Company Registration Number.: 2008/008787/07