

# ORAFLAM PVP-Iodine 1%w/v ANTISEPTIC GARGLE AND MOUTHWASH

Povidone 1% w/v Povidone Iodine equivalent to 0.1% w/v available Iodine

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## What ORAFLAM is used for

ORAFLAM is used for the relief, prevention and treatment of painful infection of the mouth and pharynx e.g.

- pharyngitis (inflammation of the pharynx),
- oral moniliasis (infection of the mouth and throat),
- tonsillitis (inflammation of the tonsils),
- aphthous ulcers (small, shallow lesions that develop on the soft tissues in your mouth or at the base of your gums),
- stomatitis (inflammation of the mucous membrane of the mouth),
- gingivitis (inflammation of the gums)
- other inflammatory conditions.

For oral hygiene prior to and after oral and dental surgery.

For minor irritation of the mouth and throat.

Helps to reduce or eliminate mouth odour.

## How ORAFLAM works

ORAFLAM contains povidone-iodine, which has broad spectrum germicidal activity. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. Povidone Iodine kills bacteria, viruses, fungi, spores and protozoa.

## Before you use ORAFLAM

- When you must not use it

- Do not take ORAFLAM if you have hypersensitivity to Povidone Iodine.
- Avoid using in people with thyroid disorder
- Avoid using ORAFLAM in large areas of broken skin.
- People who are on radioactive iodine treatment
- If you are pregnant or breastfeeding, please consult your doctor or healthcare professional before taking this product.
- Not to be used in neonates and children under 1 year of age.

- Before you start use it

If possible, consult a doctor or pharmacist.

Not suitable for use in children between 1 to 6 years old. Consult your doctor first.

- Taking other medicines

- Use with concurrent lithium therapy has been shown to exhibit additive hypothyroidic effects.
- Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests.

## How to use ORAFLAM

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Use full strength or diluted with an equal volume of water. Gargle or rinse for at least 30 seconds. Repeat every 6 hours or as directed.

- When to use it

Use as directed by your doctor or pharmacist

- How long to use it

As per the dosage recommendation

- If you forget to use it

Use immediately as soon as you remember.

- If you use too much (overdose)

In an unlikely event, if you should experience any of the following symptoms: vomiting, diarrhea, abdominal pain, fever, low blood pressure, failure of the kidney to produce urine, an abnormally rapid heart rate, shock and too much acid in the body fluid, consult your doctor immediately.

## While you are using it

- Things you must do

Take your dose exactly as given in the leaflet.

- Things you must not do

Do not use the product after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of the month.

- Things to be careful of

For External use only. Do not swallow.

Discontinue use in rare case of local sensitivity.

## Side effects

Like all medicines, ORAFLAM can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any below side effects after taking this product.

## Uncommon

- Anaphylactic and anaphylactoid reactions (Sudden, widespread, potentially severe and life-threatening allergic reactions.)
- Anaphylactic shock (an extreme, often life-threatening allergic reaction to an antigen to which the body has become hypersensitive)

## Rare

- Local Irritation
- Skin burns

Excess iodine can produce goitre (abnormal enlargement of your

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thyroid gland) and hypothyroidism (abnormally low activity of the thyroid gland) or hyperthyroidism

(abnormally high activity of the thyroid gland)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of ORAFLAM

### - *Storage*

Store below 30°C, away from direct sunlight

### - *Disposal*

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 to protect the environment.

## Product Description

### - *What it looks like*

Reddish brown solution with odor of iodine.

### - *Ingredients*

#### - Active ingredient

- Povidone Iodine

#### - Inactive ingredients

- Ethanol
- Menthol
- Saccharin Sodium
- Methyl Salicylate
- Sodium Hydroxide
- Glycerin

### - *MAL number:*

MAL20172748XZ

## Manufacturer:

PAHANG PHARMACY SDN.  
BHD. (10826-K)  
Lot 5979, Jalan Teratai,  
5 ½ Miles off Jalan Meru,  
41050 Klang,  
Selangor Darul Ehsan, Malaysia.

## Product Registration Holder:

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## Date of revision

09/12/2023

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