

Submission date:

22 May 2026

Module 1.3.2.1 PIL approved

Applicant:

Adcock Ingram Limited

Proprietary name and dosage form:

Dynexan (Ointment)

Strength:

Each 10 g contains 50 mg tetracaine hydrochloride and extract of chamomile, arnica and salvia with aluminium triformate 1 g

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S1**

DYNEXAN, each ointment contains:

Tetracaine hydrochloride 50mg and

Extract of chamomile, arnica and

salvia with aluminium triformate 1 g

DYNEXAN is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use DYNEXAN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DYNEXAN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What DYNEXAN is and what it is used for

DYNEXAN contains tetracaine hydrochloride and extract of chamomile, arnica and salvia with aluminium triformate which belongs to a group of medicine referred to as surface anaesthetics.

DYNEXAN is used for painful and inflammatory affections of:

- the lips
- the oral mucous membrane and the gums
- for relief of cold sores
- mouth ulcers
- and denture irritation.

2. What you need to know before you use DYNEXAN

Do not use DYNEXAN

- If you are hypersensitive (allergic) to Tetracaine hydrochloride, Extract of chamomile, arnica and salvia with aluminium trifluoride or any of the other ingredients of DYNEXAN ointment (listed in section 6.1).
- If you are allergic to any local anaesthetics of the ester type and to paraaminobenzoic acid and its derivatives.
- If you have low plasma-cholinesterase concentrations or are receiving anticholinesterases.

Warnings and Precautions

Special care should be taken with DYNEXAN

- If you have allergic reaction.
- The application of local anaesthetics to the skin for prolonged periods or to extensive areas should be avoided.
- If you have epilepsy, irregular heartbeats, shock or liver damage.
- If you have muscle weakness.
- If you are under 2 years of age.
- Swallowing may be impaired and it is advisable not to eat immediately after application.

Use in children and adolescents

Do not give DYNEXAN to children under the age of 2 years.

Other medicines and DYNEXAN

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

Caution must be taken when using DYNEXAN ointment as tetracaine hydrochloride may decrease the effect of sulphonamides.

DYNEXAN with food and drink

No known interactions with food and drink.

Pregnancy and breastfeeding and fertility

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 health care provider for advice before taking this medicine.

Driving and using machines

The effect on ability driving and using of machines has not been established.

3. How to take DYNEXAN

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

Always use DYNEXAN exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 2 years of age and older

Apply a pea-sized quantity of DYNEXAN ointment on the affected part three times daily at intervals of 5 to 7 hours.

If massaging is essential and possible, a pin-head sized quantity of DYNEXAN ointment should be massaged in several times a day.

When wearing new dental prostheses, the gums, palate and the prosthesis should be covered with a thin layer of DYNEXAN ointment.

Do not exceed the recommended dose.

If you take more DYNEXAN than you should

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

The most likely symptoms of overdosage are numbness of the tongue and perioral region (lower face) may appear as an early sign of systemic toxicity, restlessness, excitement, nervousness, dizziness, ringing in the ear, blurred vision, nausea and vomiting, muscle twitching, tremors and convulsions may also occur. Excitation may be temporary and followed by depression, with drowsiness, respiratory failure and coma. Cardiovascular effects may occur including low blood pressure, slow heart rate, irregular heartbeat and heart attack.

If you forget to take DYNEXAN

If you miss a treatment, apply the cream as soon as you remember, and apply the remaining doses for that day at evenly spaced intervals.

4. Possible side effects

DYNEXAN can have side effects.

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

Side effects includes:

- Blood disorder presenting with symptoms that include headache, dizziness, shortness of breath, nausea, muscle coordination and blue coloured skin, complication may include convulsions and irregular heartbeat.
- Allergic reactions may occur.
- Tetracaine is absorbed easily resulting in sudden onset of side effects, fatalities have occurred
- May cause skin irritation, retention of fluid, redness and dark patches when applied to the skin of sensitive person
- There have been reports of contact sensitivity.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of DYNEXAN.

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com.

5. How to store DYNEXAN

Store in a cool dry place (below 25 °C).

Keep tightly closed.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What DYNEXAN contains:

DYNEXAN contains the active ingredient tetracaine hydrochloride 50 mg and Extract of chamomile, arnica and salvia with aluminium triformate 1 g.

Other ingredients are:

Methyl hydroxybenzoate 0,0175 % m/m, propyl hydroxybenzoate 0,0075 % m/m, aluminium hydroxide gel, eucalyptol (Cineole), glycerol, methylcellulose methocel A4C Premium, purified water.

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What DYNEXAN looks like and contents of the pack

A smooth, cream to yellowish, homogenous preparation with an odour of eucalyptus in aluminium tube containing 10 g.

Holder of Certificate of Registration

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This leaflet was last revised in

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Registration number (s)

G2266 (Act 101/1965)