

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Diethylcarbamazine Citrate Tablets 100 mg USP*
(DEC Tablets)
diethylcarbamazine citrate

DIETHYLCARBAMAZINE CITRATE TABLETS 100 MG USP SHOULD ONLY BE USED AS PART OF A MASS DRUG ADMINISTRATION PROGRAMME FOR ELIMINATION OF LYMPHATIC FILARIASIS IN AREAS WHERE ONCHOCERCIASIS IS NOT CO-ENDEMIC. USE AS DIRECTED.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What DEC Tablets are and what they are used for
2. Before you take DEC Tablets
3. How to use DEC Tablets
4. Possible side effects
5. How to store DEC Tablets
6. Further information

1. WHAT DEC TABLETS ARE AND WHAT THEY ARE USED FOR

DEC Tablets contain the active substance diethylcarbamazine citrate which belongs to a group of medicines called antihelmintics. Diethylcarbamazine citrate acts against both larval and adult forms of parasitic worms which cause lymphatic filariasis (elephantiasis), a severely debilitating and disfiguring disease in which swelling of legs, arms, female breast or male genitals may occur.

DEC Tablets are used in adults and in children aged over 2 years for mass drug administration in communities affected by lymphatic filariasis but where river blindness (onchocerciasis) does not occur. You are being given these tablets under a mass drug administration programme in which DEC Tablets are administered every year as a single dose with albendazole 400 mg tablets for 4 to 6 years. Mass drug administration works to interfere with the transmission of disease by destroying the parasites.

2. BEFORE YOU TAKE DEC TABLETS

Do not take DEC Tablets

- if you have previously had river blindness (onchocerciasis) involving your eyes.

* Trade names are not prequalified by WHO. This is the responsibility of the local Drug Regulatory Authority. Throughout this WHOPAR the proprietary name is given as an example only.

Take special care with DEC Tablets

- if you think you may have an underlying worm infection, such as loiasis (African eye worm), onchocerciasis (river blindness) or lymphatic filariasis (elephantiasis). With an underlying worm infection, depending on the type of underlying infection, side effects may occur more frequently and may be more serious (see Section 4).
- if you have a history of epilepsy or suffer from convulsions (fits).
- if you are elderly or have heart or kidney problems you should not normally take DEC Tablets.

Taking other medicines

Please tell your healthcare provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You will not normally be given DEC Tablets if you are pregnant or breast-feeding. This is because it is not known how the tablets affect a developing baby (fetus) and it is not known if diethylcarbamazine passes into a nursing mother's breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not take DEC Tablets. Ask your healthcare provider for advice before taking any medicine.

Driving and using machines

Do not drive or use any tools or machines if you develop drowsiness after taking DEC Tablets.

Important information about some of the ingredients of DEC Tablets

DEC Tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO USE DEC TABLETS

DEC Tablets will be given to you by a health care provider as part of the mass drug administration programme.

- Always use DEC Tablets exactly as your health care provider has told you. Tablets should be swallowed in the presence of the health care provider.
- You should check with your health care provider if you are unsure of the instructions.
- DEC Tablets should preferably be taken after meals.

How much will be given

- Your health care provider will decide how much to give you.
- The usual dose in adults is 6 mg per kg body weight as a single dose administered once per year for 4-6 years.
- In children over the age of 2 years the usual dose is 6 mg per kg body weight as a single dose administered once per year for 4-6 years.
- DEC Tablets are given with albendazole 400 mg tablets (refer to the patient information for albendazole 400 mg tablets for further information).

If you take more DEC Tablets than you should

You may experience the following effects: nausea (feeling sick), vomiting, headache, vertigo (feeling dizzy), drowsiness, and, in rare but serious cases, convulsions (fits).

You should contact your health care provider if you experience any of these effects and you may be admitted to hospital for appropriate treatment, if necessary.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

DIETHYLCARBAMAZINE CITRATE TABLETS 100 MG USP SHOULD ONLY BE USED AS PART OF A MASS DRUG ADMINISTRATION PROGRAMME FOR ELIMINATION OF LYMPHATIC FILARIASIS IN AREAS WHERE ONCHOCERCIASIS IS NOT CO-ENDEMIC. USE AS DIRECTED.

Like all medicines, DEC Tablets can cause side effects, although not everybody gets them. They may happen hours or days after you have taken the tablets.

There is no clear information on how often side effects occur after taking this medicine.

When no underlying worm infection is present, side effects generally occur within one or two hours of taking the medicine and may last for a few hours. Such side effects include nausea (feeling sick), vomiting, abdominal pain, diarrhoea, loss of appetite, muscle pain, dizziness, drowsiness, fatigue and headache.

In patients with an underlying worm infection including African eye worm (loiasis), river blindness (onchocerciasis) and elephantiasis (lymphatic filariasis), side effects may be more common and serious, in particular when there is a high number of parasites in the blood. Such side effects can vary depending on the type of worm infection, may affect your whole body and may occur with or without fever (see Section 2 Take special care with DEC Tablets). These are considered to be allergic reactions to the dead worms following treatment and are particularly common in patients with river blindness infection.

When an underlying worm infection is present, side effects include irritation and swelling of the lymph nodes, abdominal pain, nausea (feeling sick), vomiting, diarrhoea, fever, chills, weakness, feeling unwell, loss of appetite, muscle pain, joint pain, chest pain, cough, dizziness, headache, fatigue, blood in the urine, irritation and swelling in and around the testicles, swelling or painful lumps developing under the skin in the scrotum, difficulty in breathing, itchiness, rash, failure of the circulation and low blood pressure upon standing.

The following side effects are associated only when an underlying African eye worm (loiasis) or river blindness (onchocerciasis) infection is present: fast heart beat, irritation or inflammation of the eye, blurred vision, eye pain, watery eyes, intolerance to light, swelling of the eye, coma, swelling of the brain, convulsions (fits), vertigo (feeling dizzy) and protein in the urine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

5. HOW TO STORE DEC TABLETS

Keep out of the sight and reach of children.

Do not store above 30°C. Keep the bottle tightly closed in order to protect from light and moisture. Discard the product 30 days after initial opening.

Do not use DEC Tablets after the expiry date, which is stated on the label after EXP. The expiry date refers to the last day of that month.

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

6. FURTHER INFORMATION

What DEC Tablets contain

- The active substance is diethylcarbamazine citrate
- The other ingredients are lactose monohydrate, corn starch, povidone (K-30), magnesium stearate and talc.

What DEC Tablets look like and contents of the pack

DEC Tablets are white to off white, uncoated, circular, flat bevelled-edged tablets debossed with “C” on one side and plain with a break line on the other side.

The tablets can be divided into equal halves.

The tablets are supplied in bulk in a white 400 cc high density polyethylene bottle with a white polypropylene cap having an induction seal and with the inclusion of two 2 gram silica gel desiccant packets. Each bottle contains 1000 tablets.

Supplier and Manufacturer

Supplier	Manufacturer
Eisai Co., Ltd. 4-6-10 Koishikawa Bunkyo-ku Tokyo 112-8088 Japan Phone: +81 3 3817 3684 Fax: +81 3 3811 2710 Email: Eisai-asia_safety@hmc.eisai.co.jp	Eisai Pharmaceuticals India Private Limited (EIL) Plot Nos. 96, 97, 98, 124 & 126 Ramky Pharma City (SEZ) Parawada-531019, Visakhapatnam District Andhra Pradesh India. Phone: : +91 8924 660777, +91 891 3047100 Fax: : +91 8924 660759

For any information about this medicinal product, please contact the local representative of the supplier:

United Kingdom

Eisai Europe Ltd
European Knowledge Centre
Mosquito Way
Hatfield
Hertfordshire
AL10 9SN
United Kingdom
tel: + 44 (0)02 8600 1400

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Detailed information on this medicine is available on the WHO Prequalification web site: <http://www.who.int/prequal/>