

PATIENT INFORMATION LEAFLET

MODET[®] 500 mg capsule **Administered orally**

Effective Substance: One capsule contains 500 mg calcium dobecylate as effective substance.

Excipients: Corn starch, magnesium stearate, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172), gelatin, indigo carmine-FD&C blue 2 (E132), iron oxide black (E172).

Please read the USAGE INSTRUCTIONS carefully before starting the use of this pharmaceutical, since it contains important information for you.

- *Keep the usage instructions. You may need to read it again later.*
- *In case you have additional questions, please consult to your physician or your pharmacist.*
- *This pharmaceutical has been personally prescribed for you; do not give it to other persons.*
- *During the use of this pharmaceutical, when you visit your physician or hospital, tell your physician that you are using this pharmaceutical.*
- *Please comply with the instructions herein. Do not use a dose, **lower or higher** than the recommended dose.*

In these Usage Instructions:

- 1. What is MODET[®] and what is it used for?**
- 2. Issues prior to the use of MODET[®]**
- 3. How is MODET[®] used?**
- 4. What are the possible side effects?**
- 5. Storage of MODET[®]**

Are explained.

1. What is MODET[®] and what is it used for?

MODET[®] is presented in blister packs, containing 60 capsules.

One capsule contains calcium dobecylate as effective substance.

Used in circulation disorders in small vessels (in particular in eye vessel disorders, related to diabetes) in circulation disorders in legs, manifesting with pain, cramps and idleness, and in addition in hemorrhoid disorders.

2. Issues prior to the use of MODET[®]

In case you have an eye disorder, related to diabetes, you must strictly comply with the diet, given by your physician to control your blood glucose levels and do not forget to use other medication, given for diabetes.

In case you have venous disease and in particular varicose veins, you must control your weight, avoid standing for a long time and keep your feet up when lying down. In case your physician has recommended certain exercises or protective socks, comply with these recommendations. In these cases, these recommendations must be observed. Using MODET® instead of these is not appropriate.

DO NOT USE MODET® in following cases:

In case you have allergy to calcium dobecylate and components of MODET®, do not use it.

USE MODET® WITH CAUTION in case of following:

If you;

- are undergoing dialysis, use MODET® only under serious medical supervision.
- In case you have symptoms during treatment, such as fever, infection in oral cavity (tonsillitis), inflammation in genital area or related symptoms, discontinue taking MODET® and inform your physician. Your physician will conduct a blood count and other tests, if necessary.
- MODET® is only used in adults.

"In case these warnings apply to you, even if for any period in the past, please consult to your physician."

Use of MODET® with food and beverage

It has no interaction with food and beverages.

Pregnancy

Please consult your physician or pharmacist before using the pharmaceutical.

MODET® must not be used during pregnancy unless necessary.

Consult your physician or your pharmacist immediately in case you realize that you are pregnant during treatment.

Lactation

Please consult your physician or pharmacist before using the pharmaceutical.

Calcium dobecylate is excreted in breast milk in small quantities. Therefore, either treatment or breastfeeding must be discontinued.

Driving and Operating Machinery

It is not possible to have any effects on the ability to drive and operate machinery.

Important information concerning some of the excipients, contained in MODET®:

No warnings are necessary for any of ingredients with respect to administration route or dose.

Use with other pharmaceuticals

There is no evidence, pointing that MODET[®] has any interactions with any pharmaceutical. *In case you are using or have recently used any prescription or over-the-counter pharmaceuticals please report these to your physician or your pharmacist.*

3. How is MODET[®] used?

Instructions for appropriate usage and dosage/application frequency:

Must always be taken as specified by your physician.

MODET[®] is only used in adults.

In general 1 or 2 capsules once or twice-a-day must be taken with meals with some water.

Highest daily dose is 4 capsules.

Dose and treatment term is determined with the suggestion of physician according to the condition to be treated.

Your physician will tell you the frequency of administration and the number of MODET[®] capsules to be used. According to your response to treatment, your physician may recommend a higher or a lower dose.

Do not exceed recommended dose.

Administration route and method:

MODET[®] is only for oral administration.

The capsules are swallowed with some water without being opened or chewed.

Different age groups:

Use in children:

Sufficient data to recommend a dosage regime for routine use in children (and in adolescents below 18 years of age) is currently not available.

Use in elderly:

The administration in elderly (65 years of age and over) is just like adults.

Special usage conditions:

Kidney/Liver failure: Dose must be decreased in patients with severe liver failure, receiving dialysis.

Your physician will tell you the duration of your treatment with MODET[®]. Do not terminate the treatment prematurely, because discontinuing MODET[®] treatment may cause worsening of your condition.

In case you have an impression that the effect of MODET[®] is too weak or too strong, talk to your physician or your pharmacist.

If you used more MODET[®] than you should have used:

In case you used MODET[®] at an amount that is more than you were supposed to, talk to a physician or a pharmacist.

If you forget to use MODET[®]:

Do not take double doses to compensate for forgotten doses.

If you forget to take your medication, take this dose as soon as you realize this and take the following dose at the regular time.

Effects, which may occur on termination of treatment with MODET[®]

N/A.

4. What are the possible side effects?

Like all pharmaceuticals, side effects can be seen in people that are sensitive to the contents of MODET[®].

If any of the following occurs, stop taking MODET[®] and inform your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital.

- Ulcerations on skin and throat, intestines and other mucosal membranes in connection with the decrease of white blood cells.

All these are serious side effects.

In case you have one of these, it means that you have a serious allergy to MODET[®]. You may need emergency medical attention or hospitalization.

All of these serious side effects are seen very rarely.

If any of the following occurs, call your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital:

- Rashes, fever, joint pain

These are serious side effects. Immediate medical response may be required. Serious side effects are seen very rarely.

If you experience any of the following side effects, you should inform your doctor:

- Nausea
- Diarrhea
- Vomiting

These are mild side effects of MODET[®].

In case these symptoms do not disappear automatically or cause distress, contact your physician.

In case you observe any side effects, which are not mentioned in these usage instructions, please inform your physician or your pharmacist.

5. Storage of MODET®

Keep MODET® away from reach and sight of children and in package.

Keep at room temperature below 25°C.

Use in compliance with expiry date.

Do not use MODET® after the expiry date on the package.

In case you notice irregularities on the product and/or package, do not use MODET®.

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