

PACKAGE LEAFLET: INFORMATION FOR THE USER

Deflat® 40 mg/ 1ml Drops

Deflat® 120 mg Chewable Tablets

Active substance: Simethicone.

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

- **Keep this leaflet. You may need to read it again**
- **If you have any further questions, ask your doctor or pharmacist**
- **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 you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

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1. What Deflat is and what it is used for

-Pharmacotherapeutic group:

Deflat® (Simethicone) is an antiflatulent drug

-Therapeutic Indications

Deflat® (Tablets and Drops) is indicated for the relief of painful symptoms as: sensation of pressure, fullness in the epigastrium and intestinal spasm – due to excessive accumulation of gases that may be formed in the digestive tract in the following cases:

- Air swallowing (aerophagia)
- Functional dyspepsia
- Irritable bowel syndrome
- Peptic ulcer
- Postoperative gaseous distension
- Infant colic.

Deflat® is used as a diagnostic aid to remove gases from the gastrointestinal tract before gastroscopy, x-ray examination and sonography of the spine and abdominal organs.

2. Before you use Deflat

a- Do not use Deflat:

- if You have Ileus disease.
- if You have Obstructive gastrointestinal disorders.

b- Take special care with Deflat:

- No special precautionary measures are necessary.

h □ For infants and children, do not exceed 12 doses per day of **Deflat** Drops except under the advice and supervision of a physician.

c-Taking other medicines:

No interactions with other agents have been reported.

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

d- Taking Deflat with food and drink:

Deflat[®] should be given after meals and at bedtime.

e-Pregnancy and breast-feeding:

- **Pregnancy: Category C**, there are no adequate and well controlled studies in pregnant women, use during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Lactation:** it is not expected to enter breast milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

3. How to use Deflat

Always use **Deflat** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Dosage and administration:

h □ **Deflat** Drops:

- Infants (less than 2 years): Half a dropperful (½ ml or 10 drops approx.) equivalent to 20 mg simethicone, four times daily after meals and at bedtime.
- Children (2-12 years): One dropperful (1 ml or 20 drops approx.) equivalent to 40 mg simethicone, four times daily after meals and at bedtime.
- For diagnostic purposes (endoscopic, radiological or sonographic investigations), **Deflat** drops is given as following: 50 drops 3-4 times a day on the two preceding days, and 50 drops each when fasting on the morning of the day of investigation and immediately before the investigation.
- For infants and children, it is not recommended to exceed 240 mg/day of **Deflat**, except under the advice and supervision of a physician

h □ **Deflat** Chewable Tablets:

- It is recommended to take one tablet four times daily after meals and at bedtime. Tablets are to be chewed well before being swallowed alone or with some water.
- For diagnostic purposes (endoscopic, radiological or sonographic investigations), **Deflat** tablets can be given in the recommended dosage for 2 – 3 days before the day of examination, additional tablet on the day of examination is recommended.

h □ The maximum recommended dose for adults is 500 mg in 24 hours unless directed by doctor.

- If you take more **Deflat** than you should:

Toxic effects from overdosage have not been reported.

4. Possible side effects

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

Simethicone is physiologically inert and is not absorbed from the stomach and intestines; so it has a high safety profile even when used for a long period of time.

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Deflat

- Keep out of the reach and sight of children.
- Store below 30 C
- Do not use **Deflat** after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- 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 protect the environment.

6. Further information

Deflat® Drops:

- Shake well before use.
- Fill the dropper to the recommended dosage level and dispense liquid slowly into mouth, toward inner cheek.
- To ease administration, the dose can be mixed with a little water, infant formula or other suitable liquid.
- **Deflat®** Drops contains artificial sweeteners and is suitable for diabetics.

Deflat® Chewable Tablets:

- Tablets are to be chewed well before being swallowed alone or with some water.

a-What Deflat contains:

1-Deflat Chewable Tablets:

-**The active substance** : Simethicone.

-**The other ingredients** : Tribasic calcium phosphate, mannitol, lactose monohydrate, magnesium stearate, fruit cocktail, ammonium glycyrrhizinate, and sodium saccharin.

2- Deflat Drops:

-**The active substance** : Simethicone.

-**The other ingredients** : Polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, pineapple flavour, benzoic acid, sodium benzoate, saccharin sodium and purified water.

b-What Deflat looks like and contents of the packs:

Deflat® Drops: Each 1ml of the emulsion contains 40 mg Simethicone USP in bottles of 30, 50 ml.

Deflat® Chewable Tablets: Each Chewable tablet contains 120 mg Simethicone USP in packs of 24 tablets.

(Not all packs may be marketed).

**Deflat is made by:
Hayat Pharmaceutical Industries Co. PLC
P.O.Box 1564
Amman 11118 Jordan**

This leaflet was last approved in 6/2012

(This is a medicament-keep medicaments out of the reach of children.)

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.