

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[CV004 trade name]*

dexamethasone phosphate 4 mg/mL solution for injection

2. Statement of active substance

Each mL of the solution contains 3.3 mg dexamethasone (as sodium phosphate) which is equivalent to 4 mg dexamethasone phosphate or 4.3 mg dexamethasone sodium phosphate.

3. List of excipients

Contains sodium.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Solution for injection

5 ampoules

10 ampoules

5. Method and route of administration

For intramuscular or intravenous use.

Diluted solution should be used within 24 hours when stored at 30°C.

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 25°C. Store in the original package in order to protect from light. Do not freeze. Avoid excursions above 25°C.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the supplier

Farmak JSC
63 Kyrylivska St.
Kyiv
Ukraine

12. WHO Reference Number (Prequalification Programme)

CV004

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoule

1. Name of the medicinal product and route(s) of administration

[CV004 trade name]

dexamethasone phosphate 4 mg/mL solution for injection

2. Method of administration

For intramuscular or intravenous injection.

3. Expiry date

EXP {MM YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Contents by weight, by volume, or by unit

4 mg dexamethasone phosphate (as sodium)

6. Other

Farmak JSC