

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

{Product name }, 500 mg, prolonged release tablets

{Product name }, 750 mg, prolonged release tablets

{Product name }, 1000 mg, prolonged release tablets

Metformin hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged release tablet contains:
Metformin hydrochloride.....500 mg
Equivalent to 390 mg Metformin.

Each prolonged release tablet contains:
Metformin hydrochloride.....750 mg
Equivalent to 585 mg Metformin.

Each prolonged release tablet contains:
Metformin hydrochloride.....1000 mg
Equivalent to 780 mg Metformin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

30 prolonged release tablets
60 prolonged release tablets
90 prolonged release tablets (only for the 500 mg and 1000 mg)
120 prolonged release tablets (only for the 500 mg and 1000 mg)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only. Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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 MARKETING AUTHORISATION HOLDER

SymPhar Sp. z o.o., ul. Włńska 1, 00-777 Warszawa

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]