

SCHEDULES

SCHEDULE 27

Package leaflets

PART 1

General requirements

1. The name of the medicinal product.
2. The strength and pharmaceutical form of the product.
3. Where appropriate, whether the product is intended for babies, children or adults.
4. Where the product contains up to three active substances, the common name of each active substance.
5. The pharmaco-therapeutic group, or type of activity, of the product, in terms easily comprehensible for the patient.
6. The product's therapeutic indications.
7. A list of—
 - (a) contra-indications;
 - (b) appropriate precautions for use;
 - (c) interactions with other medicinal products which may affect the action of the product;
 - (d) interactions with other substances, including alcohol, tobacco and foodstuffs, which may affect the action of the product; and
 - (e) special warnings, if any, relating to the product.
8. The list mentioned in paragraph 7 must—
 - (a) take into account the special requirements of particular categories of users (including, in particular, children, pregnant or breastfeeding women, the elderly and persons with specific pathological conditions);
 - (b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery; and
 - (c) list any excipients—
 - (i) if knowledge of the excipients is important for the safe and effective use of the product, and
 - (ii) the excipients are included in the guidance published pursuant to Article 65 of the 2001 Directive.
9. Instructions for proper use of the product including in particular—
 - (a) the dosage;
 - (b) the method and, if necessary, route of administration;

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- (c) the frequency of administration (including, if necessary, specifying times at which the product may or must be administered);
 - (d) the duration of treatment if this is to be limited;
 - (e) symptoms of an overdose and the action, if any, to be taken in case of an overdose;
 - (f) what to do if one or more doses have not been taken;
 - (g) an indication, if necessary, of the risk of withdrawal effects; and
 - (h) a specific recommendation to consult a doctor or pharmacist, as appropriate, for further explanation of the use of the product.
- 10.** A description of the adverse reactions which may occur in normal use of the medicinal product and, if necessary, the action to be taken in such a case.
- 11.** A reference to the expiry date printed on the packaging of the product with—
- (a) a warning against using the product after that date;
 - (b) if appropriate, details of special storage precautions to be taken;
 - (c) if necessary, a warning concerning visible signs of deterioration;
 - (d) the full qualitative composition (in active substances and excipients), and the quantitative composition in active substances, using common names, of each presentation of the medicinal product;
 - (e) for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;
 - (f) the name and address of the holder of the marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product and, if applicable, the name of the holder's appointed representative; and
 - (g) the name and address of the manufacturer of the product.
- 12.** Where the product is authorised under different names in different member States in accordance with Articles 28 to 39 of the 2001 Directive, a list of the names authorised in each member State.
- 13.** For medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the statement: "This medicinal product is subject to additional safety monitoring".
- 14.** The statement: "Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy."
- 15.** The date on which the package leaflet was last revised.