2001 No. 4111

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment (No. 2) Order 2001

Made - - - - - *28th November 2001*

Coming into force - - *10th December 2001*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Minister of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred on them by sections 51 and 129(4) of the Medicines Act 1968(**a**) or, as the case may be, the powers conferred by those provisions and now vested in them(**b**), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order pursuant to section 129(6) of that Act and after taking into account the advice of the Committee on Safety of Medicines and the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Order:—

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment (No. 2) Order 2001 and shall come into force on 10th December 2001.

(2) In this Order—

(a) "the principal Order" means the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(**c**);

(b) "Table A of Schedule 1" means Table A (internal or external use) of Schedule 1 to the principal Order (which specifies the class of medicinal products, other than products the subject of a product licence of right, on general sale by virtue of article 2(a) of the principal Order);

(c) "Table B of Schedule 1" means Table B (external use only) of Schedule 1 to the principal Order.

(**a**) 1968 c. 67; the expression "the appropriate Ministers", and the expression "the Health Ministers" which is relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, and by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142.

(**b**) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; and in the case of the Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**c**) S.I. 1984/769, amended by S.I. 1985/1540, 1987/910, 1989/969, 1990/1129, 1992/1535, 1994/2410, 1995/3216, 1997/2043, 1998/2170, 1999/852 and 2535, 2000/1092 and 2526, and 2001/2068.

Amendment of Table A of Schedule 1 to the principal Order

2.—(1) Table A of Schedule 1 is amended as follows—

(a) against the entry for Ibuprofen(**a**), there is inserted—

(i) in column 2, after the entry numbered "(2)", the words "(3) 2.0 per cent";

(ii) in column 3, after the entry numbered "(2)", the words "(3) Internal: liquid preparations, for the treatment of rheumatic or muscular pain, headache, dental pain, feverishness, or symptoms of colds and influenza for use in children aged under 12 years"; and

(iii) in column 4, after the entry numbered "(2)", the words "(3) 200 mg (MD) 800 mg (MDD); and

(b) against the entry for Potassium Chloride (**b**)—

(i) in column 2, the entry "0.15 per cent" is numbered "(1)"; and

(ii) in column 3, for the entry "Treatment of acute diarrhoea" there is substituted the entry "(1) Internal: for the treatment of acute diarrhoea" and, after that entry, there is inserted the entry "(2) External".

(2) In Table A of Schedule 1, there is inserted in column 1, at the appropriate place in the alphabetical order of the entries as they appear in that column, the entries set out in column 1 below, and, against those entries, there is inserted in columns 2, 3 and 4 the corresponding text in columns 2, 3 and 4 below:

Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	Maximum strength or maximum amount released	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Cetirizine Hydrochloride	10 mg	Tablets; for the symptomatic relief of perennial rhinitis, seasonal allergic rhinitis and idiopathic chronic urticaria in adults and in children aged 12 years and over	10 mg (MDD)
Ibuprofen Lysine	Equivalent to 200 mg ibuprofen	Tablets; for the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness or symptoms of colds and influenza in adults and in children aged 12 years and over	Equivalent to 400 mg ibuprofen (MD) Equivalent to 1200 mg ibuprofen (MDD)
Loratadine	10 mg	Tablets; for the symptomatic relief of perennial rhinitis, seasonal allergic rhinitis and idiopathic chronic urticaria in adults and in children aged 12 years and over	10 mg (MDD)

Amendment of Table B of Schedule 1 to the principal Order

3. In Table B of Schedule 1—

(a) there is deleted the entry "Potassium Chloride(**c**)" in column 1; and

(b) against the entry Sodium Fluoride—

(i) in column 2, the entry "0.33 per cent" is numbered "(1)" and, after that entry, there are inserted the entries "(2) 0.05 per cent", and "(3) 0.2 per cent"; and

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(**a**) Entry inserted by S.I. 1995/3216 and amended by S.I. 1999/2535.
(**b**) Entry inserted by S.I. 1998/2170.
(**c**) Entry inserted by S.I. 1994/2410.

(ii) in column 3, the entry "Dentifrice" is numbered "(1)" and, after that entry, there are inserted the entries "(2) Daily use mouth rinses for the prevention of dental caries", and "(3) Mouth rinses for other than daily use for the prevention of dental caries".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State,
28th November 2001 Department of Health

Bairbre de Brún
28th November 2001 Minister of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 ("the principal Order") which specifies classes of medicinal products which can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist (the general sale list).

Article 2 amends Table A (internal and external use) of Schedule 1 to the principal Order (medicinal products, other than products the subject of a product licence of right, on general sale)—

(a) in respect of the entry of Ibuprofen, by inserting a reference to liquid preparations of maximum strength 2.0 per cent, for internal use, for the treatment of rheumatic or muscular pain, headache, dental pain, feverishness, or symptoms of colds and influenza, for use in children aged under 12 years, with a maximum dose of 200 mg and a maximum daily dose of 800 mg;

(b) in respect of the entry for Potassium Chloride, by inserting a reference to external use;

(c) in respect of Cetirizine Hydrochloride, to insert an entry for tablets of maximum strength 10 mg, for the symptomatic relief of perennial rhinitis (persistent sneezing), seasonal allergic rhinitis (hayfever) and idiopathic chronic urticaria (itchy rashes), for use in adults and children aged 12 years and over with a maximum daily dose of 10 mg;

(d) in respect of Ibuprofen Lysine, to insert an entry for tablets of maximum strength equivalent to 200 mg ibuprofen, for the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness or symptoms of colds and influenza, for use in adults and in children aged 12 years and over, with a maximum dose equivalent to 400 mg ibuprofen and a maximum daily dose equivalent to 1200 mg ibuprofen;

(e) in respect of Loratadine, to insert an entry for tablets of maximum strength 10 mg, for the symptomatic relief of perennial rhinitis, seasonal allergic rhinitis and idiopathic chronic urticaria, for use in adults and children aged 12 years and over with a maximum daily dose of 10 mg.

Article 3 amends Table B (external use only) of Schedule 1 to the principal Order by deleting the entry in respect of Potassium Chloride and by amending the entries in respect of Sodium Fluoride to add Sodium Fluoride in the form of mouth rinses.

An assessment of the cost to business of complying with this Order has been made, copies of which have been placed in the libraries of both Houses of Parliament. Further copies may be obtained from the Department of Health, Medicines Control Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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