

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Nurofen for Children 40 mg/ml oral suspension

For use in children from 5 kg body weight (3 months) to 40 kg body weight (12 years)

Orange flavour

Ibuprofen

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 1ml oral suspension contains 40mg ibuprofen

3. LIST OF EXCIPIENTS

Contains Maltitol Liquid, sodium and wheat starch

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral suspension

30 ml

50 ml

100 ml

150 ml

200 ml

Syringe (5ml syringe, graduated to 1.25ml, 2.5ml, 3.75ml and 5.0ml)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

Read the leaflet before use.

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

Keep out of sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not exceed the stated dose.

8. EXPIRY DATE

EXP

After first opening: 6 month.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

[To be completed nationally]

Syringe

CE mark with the notified body under the CE marking.
The CE mark relates to the measuring syringe only.

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

For products not subject to medicinal prescription the following text will be incorporated on the labelling. For those markets where the product is subject the prescription this section will be left blank

For use in children from 3 months to 12 years

For the short term treatment of mild to moderate pain and fever

Always take Nurofen for Children exactly as indicated. You should check with your doctor or pharmacist if you are unsure.

The usual dose for pain and fever:

Child's weight (age)	How much?	How often in 24h?
From 5 kg (3 - 5 months)	1.25 ml	3 times
7-9 kg (6 - 11 months)	1.25 ml	3-4 times
10-15 kg (1 - 3 years)	2.5 ml	3 - 4 times
16-19 kg (4 - 5 years)	3.75 ml	3 times

20-29 kg (6 – 9 years)	5 ml	3 times
30-40 kg (10 – 12 years)	7.5 ml (use syringe twice: 5ml + 2.5ml)	3 times

*Doses should be given approximately every 6 to 8 hours.

For infants aged 3-5 months: If symptoms worsen or persist for more than 24 hours, medical advice should be sought

For children aged between 6 months and 12 years: If symptoms worsen or persist for more than 3 days, medical advice should be sought

Not recommended for children under 3 months of age or under 5 kg

WARNING: do not exceed the stated dose.