



## OTC USE IN NORWAY FOR IBUPROFEN, ATC-CODE: M01AE01

- To gain OTC prescription status for a medicinal product an application in accordance with “A guideline on changing the classification for the supply of a medicinal product for human use” should be submitted.
- This substance report presents the preferred wording for PIL and packaging material for OTC prescription status for ibuprofen in Norway.
- To make use of this report, the application for OTC prescription status must be:
  - within the scope of what is already approved as OTC use for ibuprofen in Norway
  - covered in the approved and/or sought SPC for the product in question

### **Tablet**

200 mg

400 mg

### **Film-coated tablet**

200 mg

400 mg

### **Effervescent tablet**

200 mg

### **Chewable capsule**

100 mg

### **Capsule, soft**

200 mg

400 mg

### **Oral suspension**

20 mg/ml

40 mg/ml

### **Oral powder**

200 mg

400 mg

## **PACKAGE LEAFLET INFORMATION**

### **INDICATION**

Voksne og barn over {body weight} kg ({years written as a number} år): korttidsbehandling av



- milde til moderate smerter, som for eksempel hodepine, menstruasjonssmerter, tannpine, muskelsmerter og leddsmerter
- feber for eksempel ved forkjølelse og influensa

Ved høy feber må lege kontaktes.

## DOSAGE

*The quantity shall be transformed from mg to the number of entities to be taken (e.g. 1-2 tablets, 1 suppository, 20 ml...) in the PIL. Include only the age group(s) for which the pharmaceutical form and strength is suitable. The table is not intended to be included in the PIL.*

### For all pharmaceutical forms:

Til barn anbefales det at dosen beregnes ut fra barnets vekt: 5-10 mg pr. kg kroppsvekt. 3 -4 ganger daglig. Den vanlige anbefalte døgndose er 20 til 30 mg pr. kg kroppsvekt. Anbefalt dose er angitt nedenfor:

<b>Kg</b>	<b>Age</b>	<b>Recommended single dose</b>	<b>Max mg/24 h</b>	<b>Approved pharmaceutical forms</b>
10-20 kg	1-6 years	100 mg every 6-8 hours	400 mg	20 mg/ml oral suspension
20 – 29kg	6-9 years	200 mg every 6-8 hours	600 mg	200 mg, 400 mg tablets*; 200 mg, 400 mg film-coated tablets*; 200 mg effervescent tablets; 200 mg soft capsule; 20 mg/ml oral suspension; 200 mg oral powder
29 – 40 kg	9-12 years	200-300 mg every 4-6 hours	900 mg	200 mg, 400 mg tablets*; 200 mg, 400 mg film-coated tablets*; 200 mg effervescent tablets; 200 mg soft capsule; 20 mg/ml oral suspension; 200 mg oral powder
Over 40 kg	Above 12 years	200-400 mg every 4-6 hours	1200 mg	200 mg, 400 mg tablets; 200 mg, 400 mg film-coated tablets;



				200 mg effervescent tablets; 200 mg , 400 mg soft capsules; 20 mg/ml oral suspension; 200 mg, 400 mg oral powder
<i>*Provided that the tablets can be divided into equal doses in accordance with European Pharmacopoeia 7.0 01/2008:0478</i>				
<u>Dosage example:</u> <i>Barn 10-20 kg (1-6 år): 100 mg hver 6-8 time. Gi ikke mer enn 400 mg i løpet av 24 timer.</i>				

Kontakt lege etter 3 dager med feber eller 5 dager med smerte hvis plagene blir verre eller ikke blir bedre.

#### **For oral suspension:**

Bruk måleredskap.

### **LABELLING INFORMATION**

#### **INDICATION**

*The indication should be written as in the PL. If the indication is written on the back side of the package the following short form should be written on the front side:*

Smertestillende, febernedsettende

#### **DOSAGE**

*The dosage should be written as in the PIL; however shortened if needed.*

#### **OTHER INFORMATION**

Skal ikke brukes av personer med magesår, eller dersom acetylsalisylsyre, ibuprofen eller andre smertestillende og febernedsettende legemidler har forårsaket astma eller allergiske reaksjoner. Til barn og gravide etter avtale med lege. Skal ikke brukes av gravide i de siste 3 måneder før fødselen. Ved langvarig feber eller smerte bør lege kontaktes.



**PACK SIZE**

<b>Pharmaceutical form</b>	<b>Strength</b>	<b>Maximum pack size</b>
Tablet	200 mg	20
Tablet	400 mg	20
Film-coated tablet	200 mg	20
Film-coated tablet	400 mg	20
Effervescent tablet	200 mg	20
Chewable capsules	100 mg	20
Soft capsules	200 mg	20
Soft capsules	400 mg	20
Oral suspension	20 mg/ml	100 ml
Oral suspension	40 mg/ml	150 ml
Oral powder	200 mg	20
Oral powder	400 mg	20

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