



IRISH MEDICINES BOARD

12 March, 2012

IRISH MEDICINES BOARD ANNOUNCES NEW DOSAGE INSTRUCTIONS FOR CHILDREN'S LIQUID PARACETAMOL MEDICINES

The Irish Medicines Board (IMB) announced today that new dosage instructions for children's liquid paracetamol medicines* will appear on product information (package leaflets and labels) within the coming weeks. The updated information will include more precise age and dosage bands to ensure that children get the most effective amount of medicine for their needs whilst making it easier for parents and carers to know how much paracetamol they should give their children.

According to Ms Ann O'Connor, IMB Director of Human Products Authorisation, the new dosage instructions for liquid paracetamol are not linked to safety issues but are being introduced as a proactive measure to optimise the effectiveness of these medicines for children. Liquid paracetamol continues to be a safe and effective treatment for pain and fever in children. "In advance of the new product information becoming available, we are advising parents and carers to continue to follow the dosage instructions provided with current packs."

The new instructions will include narrower age bands and will define a single dose per age band.

"As a result, parents can be confident that their children are getting the most effective amount of paracetamol for their age. We anticipate that medicines containing these updated instructions on the product information will be available in pharmacies and stores later this month or early April. All companies supplying the Irish market with liquid paracetamol medicines for children have adopted our recommendations," says Ms O'Connor.

"This is a prudent measure which is being taken to make it easier for parents and carers to identify how much paracetamol they can give to their children. This is not a safety issue and parents should have no concerns about following the current dosage instructions. However, these are simple changes that enhance the current advice. As with all medicines, the goal is to maximise the benefits of use and reduce the risks."

The IMB always emphasises the importance of paying close attention to the recommended directions for use of all medicines. Parents and carers are reminded to carefully read the product information (package leaflet and label) and to ensure that the maximum daily dose recommended on the packaging is never exceeded.

Parents and carers are encouraged to consult their pharmacist or doctor should they require further advice.

ENDS

FOR FURTHER INFORMATION:

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NOTES TO EDITOR:

- Single-constituent liquid paracetamol medicines have established use in Ireland over many decades.
- Measuring devices, such as a syringe or plastic spoon, are provided with liquid paracetamol medicines for children. It is important that these devices are used to measure the amount of medicines needed by a child. Parents can then be confident that they are giving the correct dose.

New Age and Dosage Bands

The new dosage schedule introduces narrower age bands and will define a single dose per age band.

(1) Infant paracetamol suspension (120 mg/5mL)

Under the current dosage instructions, liquid paracetamol-containing medicines (**120mg/5mL**) have two single age bands ranging from 3 months to 1 year and from 1 year to 6 years. In the updated instructions, there will be four separate age bands of 3-6 months, 6-24 months, 2-4 years and 4-6 years with one dose recommended for each age band as follows:

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5 mL	4 times in 24 hours
6 – 24 months	5 mL	4 times in 24 hours
2 – 4 years	7.5 mL	4 times in 24 hours
4 – 6 years	10 mL	4 times in 24 hours

(2) Paracetamol six plus suspension (250 mg/5mL)

For liquid paracetamol-containing medicines for children aged over 6 years (**250mg/5mL**), the following new age bands and doses will apply:

Child's Age	How Much	How often (in 24 hours)
6 – 8 years	5 mL	4 times in 24 hours
8 – 10 years	7.5 mL	4 times in 24 hours
10 – 12 years	10 mL	4 times in 24 hours

***List of Medicines Affected**

- CALPOL 120mg/5ml Oral Suspension
- CALPOL 120 mg/5ml INFANT ORAL SUSPENSION. 120 Oral Suspension
- CALPOL SUGAR FREE INFANT 120mg/5ml Oral Suspension
- CALPOL SIX PLUS 250mg/5ml Oral Suspension
- CALPOL SIX PLUS 250mg/5ml Oral Suspension
- MEDINOL UNDER 6 PARACETAMOL ORAL SUSPENSION 120 mg/5ml Oral Suspension
- MEDINOL OVER 6 250mg/5ml Oral Suspension
- PANADOL BABY 120mg/5mL, ORAL SUSPENSION
- PARACETAMOL INFANT 120mg/5ml Oral Suspension
- PARACETAMOL SUGAR FREE INFANT 120mg/5ml Oral Suspension
- PARALINK PARACETAMOL ORAL SOLUTION 120mg/5ml
- PARALINK SIX PLUS PARACETAMOL 250 mg/5 ml Oral Solution
- JUNIOR PARAPAED PARACETAMOL ORAL SUSPENSION 120 mg/5 ml
- SIX PLUS PARAPAED PARACETAMOL ORAL SUSPENSION 250 mg/5 ml

ABOUT THE IRISH MEDICINES BOARD

The Irish Medicines Board (IMB) is the competent authority for the licensing of human and veterinary medicines and medical devices in Ireland. Its role is to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products.