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27th January 2015

CALPOL oral suspensions: Change in Legal status to OTC

Dear Healthcare Professional,

This letter is being sent to inform you of the following:

- **The legal status for all Calpol oral suspension has been changed from POM to OTC**
- **A phasing out period of the current Calpol packs will take place over the next few months**

FURTHER INFORMATION

The Medicines Authority has reviewed and approved the OTC use for all Calpol oral suspensions. Therefore, a medical prescription is no longer required to dispense these products.

Full prescribing information can be obtained from the Medical Department at GlaxoSmithKline (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi QRM 2458, Malta (Tel. 21 238131) or can be accessed through the Medicines Authority website at: http://www.medicinesauthority.gov.mt/advanced-search

A phasing out period of the current Calpol oral suspension packs will take place over the next few months. An updated pack reflecting the updated product information will be available on the market in due course. In the meantime, the changes above are in effect and should thus be taken into consideration when dispensing the current available packs.

The main updates being implemented in the **Calpol Sugar-Free Suspension** and **Calpol Infant Suspension** SPCs (Summary of Product Characteristics) are shown below:

<table>
<tr><th colspan="4">Calpol Sugar-Free Infant Suspension
Calpol Infant Suspension
Active ingredients: Paracetamol, 120mg/5ml</th></tr>
<tr><td rowspan="11">SPC Section 4.2:
Posology & Method of Administration</td><td>Age: 2-3 months</td><td colspan="2">Dose</td></tr>
<tr><td>1. Post-vaccination fever</td><td colspan="2" rowspan="2">2.5 ml
If necessary, after 4-6 hours, give a second 2.5 ml dose</td></tr>
<tr><td>2. Other causes of Pain and Fever - if your baby weighs over 4 kg and was born after 37 weeks</td></tr>
<tr><td colspan="3">• Do not give to babies less than 2 months of age.
• Do not give more than 2 doses.
• Leave at least 4 hours between doses.
• If further doses are needed, talk to your doctor or pharmacist.</td></tr>
<tr><td rowspan="2">Age: 3 months – 6 years</td><td colspan="2">Dose</td></tr>
<tr><td>How Much</td><td>How Often
(in 24 hours)</td></tr>
<tr><td>3 – 6 months</td><td>2.5 ml</td><td>4 times</td></tr>
<tr><td>6 – 24 months</td><td>5 ml</td><td>4 times</td></tr>
<tr><td>2 – 4 years</td><td>7.5 ml
(5 ml + 2.5 ml)</td><td>4 times</td></tr>
<tr><td>4 – 6 years</td><td>10 ml
(5 ml + 5 ml)</td><td>4 times</td></tr>
<tr><td colspan="3">• Do not give more than 4 doses in any 24 hour period
• Leave at least 4 hours between doses
• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist</td></tr>
<tr><td colspan="3">It is important to shake the bottle for at least 10 seconds before use.

<u>Use in the Elderly</u>
In the elderly the dosage of paracetamol is 500 mg to 1 g every 4 to 6 hours up to a maximum of 4 g daily as the rate and extent of paracetamol absorption is normal. The dosage may need to be adjusted as the plasma half-life is longer and paracetamol clearance is lower than in young adults.</td></tr>
<tr><td>SPC Section 8:
Marketing Authorisation Number</td><td colspan="3">Calpol Sugar-Free Infant Suspension: MA167/00403
Calpol Infant Suspension: MA167/00401</td></tr>
<tr><td>SPC Section 11:
Legal Status</td><td colspan="3">OTC</td></tr>
</table>

The main updates being implemented in the **Calpol 6 Plus Suspension** SPC (Summary of Product Characteristics) are shown below:

<table>
<tr><th colspan="4">Calpol 6 Plus Suspension
Active ingredients: Paracetamol, 250mg/5ml</th></tr>
<tr><td rowspan="6"></td><td rowspan="2">Age: 6 to 12 years</td><td colspan="2">Dose</td></tr>
<tr><td>How Much</td><td>How Often
(in 24 hours)</td></tr>
<tr><td>Under 6 years</td><td>Not recommended</td><td>N/A</td></tr>
<tr><td>6 – 8 years</td><td>5 ml</td><td>4 times</td></tr>
<tr><td>8 – 10 years</td><td>7.5 ml
(5 ml + 2.5 ml)</td><td>4 times</td></tr>
<tr><td>10 – 12 years</td><td>10 ml
(5 ml + 5 ml)</td><td>4 times</td></tr>
<tr><td>SPC Section 4.2:
Posology & Method of Administration</td><td colspan="3">• Do not give more than 4 doses in any 24 hour period
• Leave at least 4 hours between doses
• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist</td></tr>
<tr><td></td><td colspan="3">Children aged 12-16 years: 10 – 15ml (Two to three 5 ml doses) up to 4 times a day
Adults and children over 16 years: 10 – 20 ml (Two to four 5 ml doses) up to 4 times a day.
It is important to shake the bottle for at least 10 seconds before use.
Use in the Elderly: In the elderly the dosage of paracetamol is as for adults (500 mg to 1 g every 4 to 6 hours up to a maximum of 4 g daily) as the rate and extent of paracetamol absorption is normal. The dosage may need to be adjusted in the elderly as the plasma half-life is longer and paracetamol clearance is lower than in young adults.

The dosage should not be continued for more than 3 days without consulting a doctor.
For oral administration</td></tr>
<tr><td>SPC Section 8:
Marketing Authorisation Number</td><td colspan="3">MA167/00402</td></tr>
<tr><td>SPC Section 11:
Legal Status</td><td colspan="3">OTC</td></tr>
</table>

CALL FOR REPORTING

Please do not forget to report any suspected adverse events to GSK (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi, QRM 2458; by phone to 21238131.

Any suspected adverse reaction and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt. When reporting please provide as much information as possible, including information about medical history, concomitant medications, onset and treatment dates.

Yours sincerely

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