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3 July 2015

CALPOL oral suspensions:
Delay in pack updates reflecting change in OTC Legal status

Dear Healthcare Professional,

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

- **In January 2015, GSK Malta communicated the legal status change from POM *(Prescription only Medication)* to OTC *(Over-the-Counter)* for all Calpol oral suspensions**
- **Due to unforeseen circumstances, the outer cartons, bottle labels and patient information leaflets of the impacted packs have not yet been updated to reflect the OTC switch**
- **In agreement with the Medicines Authority, the updated packs will be made available on the local market by end of 2015**
- **OTC legal status and Prescribing Information of all Calpol Oral Suspensions remains unchanged from the January 2015 communication**

FURTHER INFORMATION

Products in scope of this communication:
- *Calpol Sugar-Free Infant Suspension*
- *Calpol Infant Suspension*
- *Calpol 6 Plus Suspension*

In late 2014, the Medicines Authority approved the OTC use for all Calpol oral suspensions. As per local requirements, pack updates to the outer cartons, bottle label and patient information leaflets were required to be implemented within 6 months of this approval. Due to unforeseen circumstances, these changes have not been implemented to date.

In agreement with the Medicines Authority, a phasing out period of the current Calpol packs will take place over the next few months and the updated packs will be made available on the local market by end of 2015.

Legal status of Calpol Oral Suspensions and the Prescribing Information remains unchanged from the January 2015 communication. Full prescribing information can be obtained from 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

The following is a summary of the impacted SPC (Summary of Product Characteristics) sections as per January 2015 communication. This information reflects the currently approved Prescribing Information.

Calpol Sugar-Free Infant Suspension
Calpol Infant Suspension

Active ingredients: Paracetamol, 120mg/5ml

<table>
<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>

Calpol 6 Plus Suspension **Active ingredients: Paracetamol, 250mg/5ml**			
	Age: 6 to 12 years	**Dose**	
		How Much	**How Often** *(in 24 hours)*
	Under 6 years	Not recommended	N/A
	6 – 8 years	5 ml	4 times
	8 – 10 years	7.5 ml *(5 ml + 2.5 ml)*	4 times
	10 – 12 years	10 ml *(5 ml + 5 ml)*	4 times
SPC Section 4.2: *Posology & Method of Administration*	• 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		
	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		
SPC Section 8: *Marketing Authorisation Number*	MA167/00402		
SPC Section 11: *Legal Status*	OTC		

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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