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Change in Legal status (OTC switch) for selected indications of Actifed oral solutions

Dear Healthcare Professional,

This letter is being sent in agreement with the Medicines Authority to inform you of the following:

SUMMARY

- **The legal status for all Actifed oral solutions has been changed from POM to OTC for use in Adults and children aged 12 years and over***
- **Legal status for use in Children (aged 2 years to 11 years)** remains unchanged (POM)**
- **A phasing out period of the current Actifed packs will take place over the next few months**

FURTHER INFORMATION

The Medicines Authority has reviewed and approved the OTC use for all Actifed oral solutions for use in Adults and children aged 12 years and over*.

The legal status for use in Children (aged 2 years to 11 years)** remains unchanged (POM). Therefore, a medical prescription is still required to dispense these products for this population.

In view of these updates, 2 separate SPCs (Summary of Product Characteristics) will be available for each product; one for OTC use and one for POM use. The main updates being implemented in the SPCs (Summary of Product Characteristics) are highlighted below:

Actifed DM Linctus **Active ingredients: pseudoephedrine hydrochloride, triprolidine hydrochloride, dextromethorphan**		
	*** SPC for OTC use**	**** SPC for POM use**
SPC Section 4.2: ***Posology***	Adults (including the elderly) and children aged 12 years and over 10ml every 4-6 hours as required. Maximum daily dose: 40ml syrup in any 24 hours.	Children aged 6 to 11 years 5ml every 4-6 hours as required. Maximum daily dose: 20ml syrup in any 24 hours. Children aged 2 years to 5 years Actifed DM Cough Linctus is not suitable for administration to children aged under 6 years, except on the advice of a physician. Dosage recommendations are given below: 2.5ml every 4-6 hours as required. Maximum daily dose: 10ml syrup in any 24 hours. Actifed DM Cough Linctus should not be used in children under 2 years of age.
SPC Section 8: ***Marketing Authorisation Number***	MA167/00105	MA167/00101
SPC Section 11: ***Legal Status***	OTC	POM

Actifed Expectorant **Active ingredients: pseudoephedrine hydrochloride, triprolidine hydrochloride, guaiphenesin**		
	*** SPC for OTC use**	**** SPC for POM use**
SPC Section 4.2: *Posology*	Adults (including the elderly) and children aged 12 years and over 10ml every 4-6 hours as required. Maximum daily dose: 40ml syrup in any 24 hours.	Children aged 6 to 11 years 5ml every 4-6 hours as required. Maximum daily dose: 20ml syrup in any 24 hours. Children aged 2 years to 5 years Actifed Expectorant is not suitable for administration to children aged under 6 years, except on the advice of a physician. Dosage recommendations are given below: 2.5ml every 4-6 hours as required. Maximum daily dose: 10ml syrup in any 24 hours. Actifed Expectorant should not be used in children under 2 years of age.
SPC Section 8: *Marketing Authorisation Number*	MA167/00106	MA167/00102
SPC Section 11: *Legal Status*	OTC	POM

Actifed Syrup **Active ingredients: pseudoephedrine hydrochloride, triprolidine hydrochloride**		
	*** SPC for OTC use**	**** SPC for POM use**
SPC Section 4.2: *Posology*	Adults (including the elderly) and children aged 12 years and over 10 ml every 4-6 hours as required. Maximum daily dose: 40ml syrup in any 24 hours.	Children aged 6 to 11 years 5ml every 4-6 hours as required. Maximum daily dose: 20ml syrup in any 24 hours. Children aged 2 to 5 years Actifed Syrup is not suitable for administration to children aged under 6 years, except on the advice of a physician. Dosage recommendations are given below: 2.5 ml every 4-6 hours as required. Maximum daily dose: 10ml syrup in any 24 hours. Actifed Syrup should not be used in children under 2 years of age
SPC Section 8: *Marketing Authorisation Number*	MA167/00107	MA167/00103
SPC Section 11: *Legal Status*	OTC	POM

A phasing out period of the current Actifed oral solution 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 highlighted above will be in effect from the 16th January 2015 and should thus be taken into consideration when dispensing the current available packs.

Full prescribing information can be obtained from representatives of GlaxoSmithKline 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.

CALL FOR REPORTING

Please do not forget to report any suspected adverse events to GlaxoSmithKline (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, any concomitant medication, onset and treatment dates.

Yours sincerely

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