Saudi Pharmaceutical Industries & Medical Appliances Corporation
Saudi Joint Stock Company
Capital S. R 784.375.000

سبيماكو الدوائية
SPIMACO ADDWAEIH

الشركة السعودية للصناعات الدوائية و المستلزمات الطبية
شركة مساهمة سعودية
رأس المال ٧٨٤,٣٧٥,٠٠٠ ريال

C. R. 1010134224 Riyadh | www.spimaco.com.sa | س . ت 1010134224 الرياض - رقم العضوية 8552

Date 1435/08/07 -- 2014/06/05 : التاريخ

Ref :..... : الرقم

Subject: **IMPORTANT SAFETY UPDATE OF PRESCRIBING INFORMATION FOR (CARVIDOL®) (CARVEDILOL)**

Dear Healthcare Provider,

SPIMACO would like to inform you about important new safety information for Carvidol® (carvedilol) regarding severe cutaneous adverse reactions (SCAR), which has resulted in an update to the Warnings and Precautions and the post marketing Undesirable Effects section of Carvidol® company core data sheet (CDS) and the local summary of product characteristics (SPC) for Carvidol®.

This letter is being sent with the agreement of Saudi Food And Drug Authority (SFDA).

Summary

- Very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported during treatment with carvedilol.
- Carvedilol should be permanently discontinued in patients who experience severe cutaneous adverse reactions possibly attributable to carvedilol.

Further Information

During 24 years of post-marketing surveillance, very rare cases of severe cutaneous adverse reactions have been reported with carvedilol to the company safety database. The analysis of these cases identified one literature case with a fatal event of TEN probably causally related to treatment with carvedilol, and a second case reporting SJS possibly causally related to treatment with carvedilol.

As a consequence, the Warnings and Precautions and the Post Marketing Undesirable Effects section of Carvidol company core data sheet (CDS) and of the local summary of product characteristics (SPC)have been updated with this important new safety information.

The following new informationwill be included in the local SPC for Carvidol within 3 months.

2.4 Warnings and Precautions
Severe cutaneous adverse reactions (SCARs)
Very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported during treatment with carvedilol [see section 2.6.2 Post Marketing (Undesirable Effects)]. Carvedilol should be permanently discontinued in patients who experience severe cutaneous adverse reactions possibly attributable to carvedilol.

2.6.2 Post Marketing (Undesirable Effects)
Skin and subcutaneous tissue disorders
Severe cutaneous adverse reactions (Toxic epidermal necrolysis, Stevens-Johnson syndrome (see section 2.4 Warnings and Precautions)

الإدارة العامة: ٧٩ شارع الأحساء – ص.ب. ٢٠٠٠١ الرياض ١١٤٥٥ – المملكة العربية السعودية –هاتف: ٤٧٧٤٤٨١ ١ (٩٦٦) فاكس: ٤٧٧٣٩٦١ ١ (٩٦٦)
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Reporting Adverse Events.

SPIMACO will continue to monitor the safety of Carvidol through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation. You can assist us in monitoring the safety of Carvidol by reporting suspected adverse events associated with the use of Carvidol to:

The National Pharmacovigilance and Drug Safety Center.
Fax: +966-11-2057662
Email: Npc.drug@sfda.gov.sa
Online: http://ade.sfda.gov.sa

Or

Pharmacovigilance department in SPIMACO:

Address: SPIMACO ADDWAEIH, P.O.Box 2001 Riyadh 11455 Saudi Arabia
Tel: +966 114774481 Ext 1511, 1512
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Sincerely Yours,

For Ahmed Farouk

Ph. Khalid S. Al-Shamari
Product Development &
Regulatory Affairs Director