Drug Safety Update

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

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Contents

The Medicines and Healthcare products Regulatory Agency is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

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Brimonidine (Mirvaso▼) is a topical gel indicated for the symptomatic treatment of facial erythema of rosacea in adults. Some patients may have exacerbation or rebound symptoms of rosacea. Patients should start treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment. Further information is on page 2.

We are running a social media campaign to promote the reporting of suspected adverse drug reactions to the Yellow Card Scheme in support of an awareness week from 7 to 11 November 2016. The main message of the campaign is that reporting helps make medicines safer and saves lives. See page 3 for further information on how you can get involved.

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Brimonidine gel (Mirvaso▼): risk of exacerbation of rosacea

Some patients may have exacerbation or rebound symptoms of rosacea. It is important to initiate treatment with a small amount of gel and increase the dose gradually, based on tolerability and treatment response.

Advice for healthcare professionals:

- exacerbation of rosacea symptoms occurred in up to 16% of patients treated with brimonidine gel in clinical studies; in most cases, erythema and flushing resolve after stopping treatment
- initiate treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment
- advise patients carefully on how to apply the gel and on the importance of not exceeding the maximum daily dose (which is 1 g of gel in total weight, approximately 5 pea-sized amounts)
- advise patients to stop treatment and consult a doctor if their symptoms worsen during treatment (increased redness or burning)

Brimonidine (Mirvaso▼) is a topical gel indicated for the symptomatic treatment of facial erythema of rosacea in adults.

Risk of symptom exacerbation

Symptom exacerbation has been reported very commonly in patients treated with brimonidine gel, including cases of a rebound effect after the therapeutic effect wears off (approximately 8–12 hours after application) and cases in which exacerbation of symptoms (particularly erythema and flushing) occurred during treatment soon after it was applied.

Across all clinical studies, 16% of patients who were receiving brimonidine gel had symptom exacerbation. Most patients recovered on stopping treatment. The potential mechanism is currently unknown.

New prescribing advice

Following an EU-wide review, prescribing advice has been updated. Patients should start treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment. This will help enable patients to find the best balance between therapeutic and adverse effects.

Before prescribing, healthcare professionals should carefully advise patients on how to apply the gel and build up the dose gradually. They should be informed not to exceed the maximum daily dose (1 g of gel in total weight,

approximately 5 pea-sized amounts). Patients should be warned to stop treatment and see their doctor if worsening of rosacea symptoms occurs.

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Show your support for reporting suspected adverse drug reactions

We are running a social media campaign to promote the reporting of suspected adverse drug reactions to the Yellow Card Scheme in support of an awareness week from 7 to 11 November 2016. The main message of the campaign is that reporting helps make medicines safer and saves lives.

What can healthcare professionals and their organisations do?

- follow us on our social media channels and show your support for the importance of reporting adverse drug reactions (ADRs) by retweeting, commenting, liking, and sharing material with your social media contacts. You can follow us via:
  - Twitter (@MHRAgovuk and @MHRAmedicines)
  - YouTube
  - Facebook
  - LinkedIn

- encourage dialogue between your colleagues and your patients about the importance of reporting suspected ADRs. Engage locally with your regional Yellow Card Centre or your local Medication Safety Officer (MSO) in England at your hospital trust

- don't wait to report any suspected ADRs to the Yellow Card Scheme

Campaign material for the awareness week includes animations and infographics, and is available on the Yellow Card reporting website.

The reporting of suspected ADRs is key to patient safety. This campaign—the first of its kind in Europe—will help encourage greater local and national awareness about the importance of reporting to support the earlier detection of safety issues.

We also have dedicated guidance on the Yellow Card scheme for healthcare professionals.

In addition to suspected adverse reactions to medicines, the Yellow Card scheme also collects reports on potential problems or incidents involving medical devices, defective medicines, counterfeits, herbal and homeopathic products, and e-cigarettes or their refill containers (e-liquids).

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Letters sent to healthcare professionals in October 2016

In October 2016, the following letters were sent to relevant healthcare professionals:

- Flolan (epoprostenol): new thermostable formulation (solvent pH 12) available from October 2016, with differences in storage and administration from previous formulation (pH 10.5)
- Teva levothyroxine: reintroduction to market and introduction of new tablet strengths (letter for Clinical Commissioning Groups, and for pharmacists and dispensers); see also further information here
- Blincyto▼ (blinatumomab): cases of pancreatitis

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