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Reminyl® (galantamine hydrobromide): serious skin reactions (Stevens-Johnson syndrome, acute generalised exanthematous pustulosis, erythema multiforme)

Dear Healthcare Professional,

Shire Pharmaceuticals Limited would like to inform you of the following:

Summary

- Serious skin reactions have been reported in people taking galantamine hydrobromide (Reminyl). These included Stevens Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP) and erythema multiforme (EM).

- Tell patients and carers to watch out for signs of serious skin reactions, including:
    - severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
    - red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).
    - rash that may blister, with spots that look like small targets (erythema multiforme).

- Tell patients and carers to stop galantamine hydrobromide treatment and get medical help immediately if they notice any of the above signs.

Further information

Galantamine hydrobromide is indicated for the treatment of mild to moderately severe dementia of the Alzheimer type.

To date, we have identified 5 cases of serious skin reactions worldwide with symptoms of AGEP, SJS or EM in patients taking galantamine hydrobromide. We identified these cases from scientific literature and reports submitted to us by healthcare professionals. As a result of these findings, we are issuing the new prescribing advice outlined above.

We have also updated the product information to include SJS, AGEP and EM as potential adverse drug reactions (ADRs). Please refer to the Summary of Product Characteristics and Patient Information Leaflet (Annex) for the specific changes.

Call for reporting
Please continue to report suspected ADRs to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/

Alternatively, prepaid Yellow Cards for reporting are available:

- at the back of the British National Formulary (BNF)
- by emailing yellowcard@mhra.gsi.gov.uk
- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the MHRA website https://yellowcard.mhra.gov.uk/downloadable-information/

When reporting please provide as much information as possible, including medical history, any concomitant medication, ADR onset time, treatment dates, and product brand name.

ADRs can also be reported to Shire:
e-mail: GlobalPharmacovigilance@shire.com
Tel. number: +44 1256 894000
Fax number: +44 1256 894715

Company contact point
For questions relating to the content of this letter please contact the Shire Medical Information Department:
Tel: 0800 055 6614
Email: medinfoeuceemea@shire.com

Address:
Shire Pharmaceutical Contracts Limited
Hampshire International Business Park
Chineham, Basingstoke
Hampshire
RG248EP
United Kingdom.

Yours faithfully,

Calum Sinclair,
EEA Qualified Person for Pharmacovigilance

Dr Peter Gillberg
Medical Director

Annex

Additions to the galantamine hydrobromide Summary of Product Characteristics:

Section 4.4 Special warnings and precautions for use

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Serious skin reactions
Serious skin reactions (Stevens Johnson syndrome and acute generalized exanthematous pustulosis) have been reported in patients receiving Reminyl (see section 4.8). It is recommended that patients be informed about the signs of serious skin reactions, and that use of Reminyl be discontinued at the first appearance of skin rash
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Section 4.8 Undesirable effects
Skin and subcutaneous tissue disorder, rare, Stevens-Johnson Syndrome; Acute Generalized exthematous Pustulosis; Erythema multiforme.

Additions to the galantamine hydrobromide Patient Information Leaflet:

(additions are underlined)

Section 2 What you need to know before you take Reminyl
Warnings and precautions
[...]
Serious side effects
Reminyl can cause serious skin reactions, heart problems and fits (seizures). You must be aware of these effects while you are taking Reminyl. See 'Look out for serious side effects' in section 4.

Section 4 Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. Look out for serious side effects.

Stop taking Reminyl and see a doctor or go to your nearest emergency department immediately if you notice any of the following.

- Skin reactions, including:
  - Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
  - Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).
  - Rash that may blister, with spots that look like small targets.
- These skin reactions are rare in people taking Reminyl (may affect up to 1 in 1,000 people).
- Heart problems, including changes in heart beat (such as a slow beat, extra beats) or palpitations (heart beat feels fast or uneven). Heart problems may show as an abnormal tracing on an 'electrocardiogram' (ECG), and can be common in people taking Reminyl (may affect up to 1 in 10 people).
- Fits (seizures). These are uncommon in people taking Reminyl (may affect up to 1 in 100 people).

You must stop taking Reminyl and get help immediately if you notice any of the side effects above.
[...]