QNasl (beclomethasone dipropionate) Nasal Aerosol

Full Safety and Drug Utilization Review Provided in Background Materials

Pediatric Advisory Committee Meeting, March 24, 2015
QNASL - Background

- QNASL was first approved 3/23/2012 and is indicated for treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents ≥12 years of age.
- QNASL was approved in December 2014 for use in children 4-11 years.
- QNASL was to go to the September 2014 PAC, but one PAC member voted that QNASL be presented at a future PAC so that all PAC members could discuss and make recommendations.
- A full safety and utilization review was conducted. FDA did not identify any new pediatric safety issues of concern. The review and updated memo are provided in the background materials.
No new safety signal identified

- FAERS reports 3/1/2012 – 12/31/2014, no deaths
  - 7 adverse events (2 serious, 5 non-serious)
  - 2 serious: 1 with neck swelling and urticaria*; 1 with increased hyperactivity and combative behavior**
  - 5 non-serious: 2 nasal burning sensation, 1 each with epistaxis, nasal congestion, and pain

*Hypersensitivity is in Warning and Precautions of label
**The case with hyperactivity and combative behavior had incomplete information to assess causation.
QNDSL – Pediatric Drug Utilization Review

Nationally estimated number of unique patients, stratified by patient age*, who received Qnasl prescriptions dispensed from U.S. outpatient retail pharmacies

<table>
<thead>
<tr>
<th>Mar 2012 – Dec 2013</th>
<th>Patients (N)</th>
<th>Share (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grand Total</td>
<td>208,662</td>
<td>100.0%</td>
</tr>
<tr>
<td>Age 0-16 years</td>
<td>24,593</td>
<td>11.8%</td>
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<tr>
<td>Age 0-11 years</td>
<td>9,915</td>
<td>40.3%</td>
</tr>
<tr>
<td>Age 12-16 years</td>
<td>14,979</td>
<td>60.9%</td>
</tr>
<tr>
<td>Age 17+ years</td>
<td>184,157</td>
<td>88.2%</td>
</tr>
<tr>
<td>Unknown Age</td>
<td>23</td>
<td>&lt;0.1%</td>
</tr>
</tbody>
</table>

*Patient age subtotals may not sum exactly due to patients aging during the study and may be counted more than once in the individual age categories. Summing across patient age bands is not advisable and will result in overestimates of patient counts.


- Pediatric patients 0-16 years accounted for ~12% (25,000) of patients.
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FDA will continue its standard ongoing safety monitoring.

Does the Committee concur?