

7th May 07

For the attention of Ophthalmologists:

Re: Serious adverse reactions associated with intra-ocular administration of Adcortyl/Kenalog Injections

Bristol-Myers Squibb Pharmaceuticals wish to inform you of important safety information regarding the route of administration of ADCORTYL & KENALOG INJECTIONS (triamcinolone acetonide). These are suspensions formulated with benzyl alcohol as a preservative. ADCORTYL 10MG/ML INJECTION is approved for intra-articular and intradermal use and KENALOG 40MG/ML INJECTION is approved for intra-articular and intramuscular use.

In post-marketing experience worldwide, cases of endophthalmitis, eye inflammation, increased intraocular pressure and visual disturbances including vision loss have been reported in patients following intraocular (intravitreal) administration of ADCORTYL & KENALOG INJECTIONS.

Intraocular administration is *not* an approved route of administration of ADCORTYL & KENALOG INJECTIONS.

- Adequate studies to demonstrate the safety of ADCORTYL & KENALOG INJECTIONS use by intratubinal, subconjunctival, sub-Tenons, retrobulbar and intraocular (intravitreal) injections have not been performed
- Endophthalmitis, eye inflammation, increased intraocular pressure and visual disturbances including vision loss have been reported with intravitreal administration of ADCORTYL & KENALOG INJECTIONS
- Administration of ADCORTYL & KENALOG INJECTIONS by intratubinal, subconjunctival, sub-Tenon, retrobulbar, and intraocular (intravitreal) routes is not recommended
- ADCORTYL & KENALOG INJECTIONS are not recommended for administration into the nasal turbinates or intralesional injection about the head

Variations to the licence have been approved by the Medicines & Healthcare products Regulatory Agency (MHRA) amending the Summaries of Product Characteristics (SPCs), to reflect the important information mentioned above.

Please refer to the enclosed Summary of Product Characteristics, also available at www.medicines.org.uk for the revised text.

If you have further questions or require additional information, please contact our Medical Information Department at 0800 7311736.

Yours sincerely

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