

# RA Subset Responds to Higher Rituximab Dose

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**H**igher-than-standard doses of rituximab improved clinical response rates in patients with rheumatoid arthritis who had an incomplete B-lymphocyte depletion as determined by highly sensitive flow cytometry, judging from results from a small study.

"Not only is B-cell depletion important in determining clinical response, it can be enhanced by increasing the dose of rituximab," according to Dr. Edward Vital of the U.K. National Institute for Health Research's Leeds (England) Musculoskeletal Biomedical Research Unit.

Rituximab is administered as two 1-g doses, "but a significant proportion [of patients] fail to achieve a EULAR response after standard therapy," he said.

Dr. Vital and his associates used highly sensitive flow cytometry to identify 26 patients with active RA and incomplete depletion 2 weeks after they received an initial 1-g dose of rituximab. The patients were then randomized 1:1 to a total of either 2 g or 3 g rituximab.

At the end of 40 weeks, a significantly higher proportion of patients who received 3 g of rituximab had EULAR moderate/good response rates, com-

pared with their counterparts who received 2 g (92% vs. 54%, respectively). Data from 1 year of follow-up on 20 of the patients showed EULAR moderate/good responses in 67% of patients who received 3 g vs. 27% in those who received 2 g. ■

**Disclosures:** Dr. Vital disclosed that he received research support from Roche to conduct the study.

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  - Contraindicated for the treatment of perioperative pain in the setting of CABG
  - In clinical trials, AEs were comparable to placebo patch
  - Most common AEs were skin reactions at the site of treatment, GI disorders, and nervous system disorders

<sup>a</sup> Clinical significance of solubility and pharmacokinetic data is unknown.

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diuretics and ACE inhibitors. FLECTOR® Patch is not recommended in patients with advanced renal disease.

Anaphylactoid reactions may occur both in patients with aspirin triad and in patients without known sensitivity to NSAIDs or prior exposure to FLECTOR® Patch. NSAIDs, including FLECTOR® Patch, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal and may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

FLECTOR® Patch should be avoided in late pregnancy because it may cause premature closure of the ductus arteriosus.

Anemia is sometimes seen in patients receiving NSAIDs, and platelet inhibition has been shown to prolong bleeding times.

Avoid concurrent use with oral NSAIDs.

Safety and effectiveness in pediatric patients have not been established.

Overall, the most common adverse events associated with FLECTOR® Patch were skin reactions (pruritus, dermatitis, burning, etc) at the site of treatment, GI disorders (nausea, dysgeusia, dyspepsia, etc), and nervous system disorders (headache, paresthesia, somnolence, etc).

Please see Brief Summary of full Prescribing Information, including boxed warning, on adjacent pages.

**References:** 1. Data on file. King Pharmaceuticals®, Inc. 2. Jenoure PJ, Rostan A, Gremion G, et al. Multicenter, double-blind, controlled clinical study on diclofenac Tissuegel plaster in patients with epicondylitis [in Italian]. *Med Sport (Roma)*. 1997;50(3):285-292. 3. Flector Patch [package insert]. Bristol, TN: King Pharmaceuticals, Inc; 2009. 4. Jousseil E. Flector Tissuegel® in the treatment of painful ankle sprain [in French]. *J Traumatol Sport*. 2003;20:155-159. 5. Rovati S, Garavani A. Research and development of a pharmaceutical technique allowing for improvement in clinical efficacy and simplicity of use of known drugs [in French]. *Tribuna Medica Ticinese*. 1996;61:204-207. 6. Fini A, Fazio G, Rapaport I. Diclofenac/N-(2-hydroxyethyl)pyrrolidine: a new salt for an old drug. *Drugs Exp Clin Res*. 1993;19(3):81-88. 7. Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. *Clin Ther*. 2001;23(8):1296-1310.



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