EXEM FOAM (air polymer-type A) intrauterine foam

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HIGHLIGHTS OF PRESCRIBING INFORMATION

The ExEm Foam kit includes the following components:

- One Combifix Adaptor (coupling device)
- One Syringe A containing 5 mL clear Gel [polymer type A (hydroxyethyl cellulose), glycerin and purified water]
- One Syringe B containing 5 mL Sterile Purified Water
- A fallopian tube is classified as occluded if ExEm Foam is observed to pass from the tube and spills into the peritoneal cavity. The fallopian tube will appear as a bright line.

To ensure that the patient is not pregnant prior to ExEm Foam administration:

- Confirm that the patient has a negative pregnancy test within the 24 hours before ExEm Foam administration.

15 PATIENT COUNSELING INFORMATION

To report SUSPECTED ADVERSE REACTIONS, contact ExEm Foam Inc. at 1-888-943-0030 (943-0030) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug may not reflect the rates observed in practice. The common adverse reactions associated with ExEm Foam when used as indicated in sonohysterosalpingography are: pelvic and abdominal pain; vasovagal reactions and symptoms such as nausea and faintness; and post-procedure spotting.

6.2 Postmarketing Experience
The following adverse reactions have been identified during post-approval use of ExEm Foam (air polymer-type A) intrauterine foam. In human subjects, the effects on the breasts were infrequent, or the effects on pelvic pain. No adverse reactions in breasts or infrequent pelvic pain are anticipated following maternal administration of ExEm Foam, based on the void safety margin for glycerol in infants and the expected negligible absorption of hydroxyethyl cellulose [see Clinical Pharmacology (12.3)]. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for ExEm Foam and any potential adverse effects on the breastfed infant from ExEm Foam or from the underlying maternal condition.

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