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## Ablavar (Gadofosveset Trisodium Injection)

??? ??????: 30 ?????2/????? 2017

The following adverse reactions are discussed in greater detail in other sections of the label:

- **WARNINGS AND PRECAUTIONS** Nephrogenic systemic fibrosis [see ]
- **WARNINGS AND PRECAUTIONS** Hypersensitivity reactions [see ]

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

### Clinical Studies Experience

**WARNINGS AND PRECAUTIONS** Anaphylaxis and anaphylactoid reactions were the most common serious reactions observed following ABLAVAR injection administration [see ].**PRECAUTIONS**

In all clinical trials evaluating ABLAVAR with MRA, a total of 1,676 (1379 patients and 297 healthy subjects) were exposed to various doses ABLAVAR. The mean age of the 1379 patients who received ABLAVAR was 63 years (range 18 to 91 years); 66% (903) were men and 34% (476) were women. In this population, there were 80% (1100) Caucasian, 8% (107) Black, 12% (159) Hispanic, 1% (7) Asian, and < 1% (6) patients of other racial or ethnic groups. Table 2 shows the most common adverse reactions ( ? 1%) experienced by subjects receiving ABLAVAR at a dose of 0.03 mmol/kg.

**Table 2 : Common Adverse Reactions in 802 Subjects Receiving ABLAVAR at 0.03 mmol/kg**

n (%)	Preferred Term
42 (5)	Pruritis
33 (4)	Headache
33 (4)	Nausea
26 (3)	Vasodilatation
25 (3)	Paresthesia
19 (2)	Injection site bruising
18 (2)	Dysgeusia
17 (2)	Burning sensation
17 (2)	Venipuncture site bruise
11 (1)	Hypertension
8 (1)	Dizziness (excluding vertigo)
7 (1)	Feeling cold

### Post-marketing Experience

Because post-marketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The profile of adverse reactions identified during the post-marketing experience outside the United States was similar to that observed during the clinical studies experience.