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Sample of Warnings in Pharmaceutical Package Inserts

<p>警告</p> <p>1. 本剤投与により、結核、肺炎、敗血症を含む重篤な感染症及び脱髄疾患の新たな発生もしくは悪化等が報告されており、本剤との関連性は明らかではないが、悪性腫瘍の発現も報告されている。本剤が疾病を完治させる薬剤でないことも含め、これらの情報を患者に十分説明し、患者が理解したことを確認した上で、治療上の有益性が危険性を上回ると判断される場合にのみ投与すること。</p> <p>また、本剤の投与において、重篤な副作用により、致命的な経過をたどることがあるので、緊急時の対応が十分可能な医療施設及び医師の管理指導のもとで使用し、本剤投与後に副作用が発現した場合には、主治医に連絡するよう患者に注意を与えること。</p> <p>2. 感染症</p> <p>(1) 重篤な感染症 敗血症、肺炎、真菌感染症を含む日和見感染症等の致命的な感染症が報告されているため、十分な観察を行うなど感染症の発症に注意すること。</p> <p>(2) 結核 播種性結核（粟粒結核）及び肺外結核（胸膜、リンパ節等）を含む結核が発症し、死亡例も認められている。結核の既感染者では症状の顕在化及び悪化のおそれがあるため、本剤投与に先立って結核に関する十分な問診及び胸部X線検査に加え、インターフェロン-<math>\gamma</math>遊離試験又はツベルクリン反応検査を行い、適宜胸部CT検査等を行う</p>	<p>Warnings</p> <p>1. Serious infectious diseases including tuberculosis, pneumonia and sepsis as well as the new onset or aggravation, etc. of demyelinating diseases have been reported due to the administration of this drug, and while the relevance to this drug is not clear, the expression of malignant tumors has also been reported. Fully explain to the patient this information, including also that this drug is not a drug that completely cures the disease, and administer it only after having confirmed that the patient has understood this and if it is determined that the benefits in therapy outweigh the risks.</p> <p>And, in the administration of this drug, it could run a fatal course due to serious adverse drug reactions, so use it at medical treatment facilities fully capable of a response in an emergency and under the management and guidance of a physician, and if an adverse drug reaction occurs after the administration of this drug, caution the patient to contact his/her primary care physician.</p> <p>2. Infectious Diseases</p> <p>(1) Serious Infectious Diseases Fatal infectious diseases have been reported such as opportunistic infections including sepsis, pneumonia or fungal infections, so be cautious of the onset of infections by fully monitoring the situation, etc.</p> <p>(2) Tuberculosis Tuberculosis has developed including disseminated tuberculosis (miliary tuberculosis) and extrapulmonary tuberculosis (pleural, lymph nodes, etc.), and cases of death have also been seen. In patients who have had prior infections of tuberculosis, there is the risk of the manifestation or aggravation of symptoms, so in advance of the administration of this drug, in addition to a full medical interview regarding tuberculosis and chest X-ray tests, perform an interferon-<math>\gamma</math> release assay or a tuberculin reaction test, and by performing an chest CT scan as necessary, confirm whether or not there is a tuberculosis infection. And, for patients who have had prior infections of tuberculosis, administer this drug after having administered an</p>
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<p>ことにより、結核感染の有無を確認すること。また、結核の既感染者には、抗結核薬の投与をした上で、本剤を投与すること。ツベルクリン反応等の検査が陰性の患者において、投与後活動性結核が認められた例も報告されている。</p> <p>3.</p> <p>脱髄疾患（多発性硬化症等）の臨床症状・画像診断上の新たな発生もしくは悪化が、本剤を含む抗 TNF 製剤でみられたとの報告がある。脱髄疾患（多発性硬化症等）及びその既往歴のある患者には投与しないこととし、脱髄疾患を疑う患者や家族歴を有する患者に投与する場合には、適宜画像診断等の検査を実施するなど、十分な観察を行うこと。</p>	<p>antituberculous drug. In patients who have negative tests such as for tuberculin reaction, cases have also been reported in which active tuberculosis has been seen after administration.</p> <p>3.</p> <p>There are reports that new onsets or aggravation have been seen in clinical symptoms or diagnostic imaging of demyelinating diseases (multiple sclerosis, etc.) with anti-TNF pharmaceutical formulations including this drug. Do not administer it to patients with demyelinating diseases (multiple sclerosis, etc.) or those who have a prior history of it, and in the case of administering it to a patient who is suspected of a demyelinating disease or a patient who has a family history of it, perform full monitoring, such as doing tests such as diagnostic imaging as necessary.</p>
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