HM848 : Deliverable 1
Evaluation of FDA Approved drug : Amgevita
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1. **Brand Name and Chemical Name**:
   - Brand Name: Amgevita
   - Chemical Name: adalimumab-atto[1]

2. **Formulation**:
   - Injection solution
   - Single-dose prefilled glass syringe or autoinjector containing 40mg/0.8mL or 20mg/0.4mL adalimumab-atto solution[2]

3. **Doses**:
   - 40 mg/0.8 mL in a single-use prefilled syringe[1]
   - 40 mg/0.8 mL in a single-use prefilled SureClick® autoinjector[1]
   - 20 mg/0.4 mL in a single-use prefilled SureClick® autoinjector[1]

4. **Storage**:
   - Amgevita should be refrigerated at 36°F to 46°F (2°C to 8°C).It should not be freezed.[1]
   - It can be kept at room temperature up to 77°F (25°C) for up to 14 days in the original carton to protect it from light.[1]

5. **Biologic**:
   - Amgevita is classified as a biologic, specifically a recombinant human IgG1 monoclonal antibody [3]

6. **Initial FDA Approval**:
   - Amgevita was initially approved for sale in the US in 2017[3]

7. **NDC Codes**:
   - NDC 55513-726-01: 40 mg/0.8 mL prefilled syringe[1]
   - NDC 55513-727-01: 40 mg/0.8 mL autoinjector[1]
   - NDC 55513-728-01: 20 mg/0.4 mL autoinjector[1]

8. **NDA/BLA of Amgevita** :
   - The New Drug Application (NDA) or Biologics License Application (BLA) for Amgevita is 761024 [3][4]

9. **Mechanism of Action**:
   - Amgevita works by binding to tumor necrosis factor (TNF) and blocking its interaction with cell surface TNF receptors, thereby reducing TNF-mediated inflammation [1].

10. **Patients**:

Amgevita is used to treat patients with following conditions [1][5]:

- Moderate to severe rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Moderate to severe Crohn's disease
- Moderate to severe ulcerative colitis
- Moderate to severe chronic plaque psoriasis
- Non-infectious intermediate uveitis
- Juvenile idiopathic arthritis

11. **Administration** :
   - Amgevita is administered by a healthcare provider as a subcutaneous injection[1].

12. **Efficacy and Safety Evidence**:
   - Five pivotal trials in rheumatoid arthritis patients showed ACR20 response rates of 58-66% compared to placebo rates of 19-36% at 24-26 weeks, indicating improved symptoms and physical function[4,6].
   - Two pivotal trials in psoriatic arthritis patients demonstrated ACR20 response rates of 58% and 57% compared to placebo rates of 14% and 15% at 12-24 weeks[4,6].

13.**Purported Harms (Side Effects)**:
According to the FDA-approved label for Amgevita, the following side effects are reported:

- **Serious Infections**: Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens[1][4].
- **Malignancy**: Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products[1][4].

14. Black Box Warning / REMS program :

- There is a black box warning for **Amgevita**. It states the risks of serious infections and malignancy (as mentioned above) and emphasizes the need for vigilance and monitoring during treatment[9].
- REMS Program:The FDA does not require a Risk Evaluation and Mitigation Strategy (REMS) program specifically for **Amgevita**[10].

15. Usage :
- It can be used alone or with other non-biologic disease-modifying antirheumatic drugs (DMARDs) like methotrexate [1]

16. Therapeutic Class:
- Amgevita belongs to the therapeutic class of TNF blockers [2, 7].

17. Labeler/Sponsor:
- The labeler/sponsor of Amgevita is Amgen Inc [1]

18. Manufacturing Facilities:
- Amgen - Puerto Rico[8]
- Boehringer Ingelheim - Germany[8]

19. Biosimilar Approval Pathway
- Amgevita was approved through the biosimilar approval pathway as a biosimilar to Humira (adalimumab) [3, 5]

Sources:
[1] FDA. "Amgevita (adalimumab-atto) Label." Accessed from https://labels.fda.gov/Label/761024Orig1s000Lbl.pdf
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[4] FDA. "Medical Review: Amgevita (adalimumab-atto)." Accessed from https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761024Orig1s000MedR.pdf
[5] FDA. "FDA Approves Amjevita, a Biosimilar to Humira." Accessed from https://www.fda.gov/news-events/press-announcements/fda-approves-amjevita-biosimilar-humira
[6] Amjevita. "Efficacy." Accessed from https://www.amjevita.com/rheumatology/efficacy
[7] Mayo Clinic. "Adalimumab (Subcutaneous Route)." Accessed from https://www.mayoclinic.org/drugs-supplements/adalimumab-subcutaneous-route/description/drg-20068487
[8] Amjevita. "About." Accessed from https://www.amjevita.com/about
[9] FDA. "Amgevita (adalimumab-atto) Label." Accessed from https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761024lbl.pdf
[10] Drugs.com. "Amjevita." Accessed from https://www.drugs.com/history/amjevita.html